Firm Information

FEI
3013856747

Firm Name
Danish Jabbar MD

Firm Physical Address
1153 E Gannon Dr, Festus, MO, 63028-2611, US

Phone

Profiled
No

Firm Mailing Address
1153 E Gannon Dr, Festus, MO, 63028-2611, US

Number of Employees

Establishment Size
(Unknown)

Responsible FDA Org
Kansas City District Office

Inspection Details

Inspection Start Date
01/02/2018

Inspection End Date
01/23/2018

Days at the Facility
4

Inspection Basis
Consumer Complaint

Endorsement
This comprehensive CDER PDUFA Domestic Clinical Investigator (CDER Priority Therapy Designation for BLA 761051) inspection was conducted per For-Cause Memorandum of Assignment dated 9/26/17, FY 18 workplan FACTS # 11775628, Operation ID 75174 and in accordance with CP 7348.811, Clinical Investigators and the specific instructions listed in the assignment.

There was no inspectional history with FDA. The current inspection covered protocols:

HS-16-555: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Enriched-Enrollment Withdrawal, Multicenter Study to Evaluate the Efficacy and Safety of a Long-Acting Subcutaneous Injectable Depot of Buprenorphine (CAM2038) in Subjects with Moderate to Severe Chronic Low Back Pain Currently Treated with Daily Opioids sponsored by Braeburn Pharmaceuticals, 47 Hulfish Street, Suite 441, Princeton, New Jersey.

CCD-05993AA3-01: An 8-week, randomized, double-blind, placebo and active-controlled, parallel group, dose ranging study to evaluate the efficacy and safety of 3 doses of CHF 718 pMDI (beclomethasone diproprionate) in asthmatic subjects sponsored by Chiesi Farmaceutici, S.p.A, Via Palermo 26/A, Parma, Italy.

This inspection covered IRB oversight, informed consent, eligibility, protocol adherence, concomitant medications, adverse events and test article accountability. The site had screened subjects for both protocols, but at the time of the inspection, had not enrolled or dosed subjects for either study. Braeburn had closed the site on 12-20-17 for lack of enrollment. At the conclusion, No FDA 483 was issued. The following items were discussed during the inspection and at close out:

1. They are responsible for utilizing Good Documentation Practices and assuring their records are accurate, complete and maintained in an accessible format for the required time. Subject ID numbers should be utilized on all paper and electronic study generated records. All study related correspondence shall be retained for each

study. Leaving correspondence and attachments in e-mail accounts does not ensure they are available for required time period.
2. Investigator is responsible for assuring duties are delegated to individuals with appropriate training and education to perform them.
3. They should keep records regarding calibration and maintenance of refrigerators, freezers and the thermometers used to monitor temperatures.
4. Specimen refrigerators and freezers should be free from food and beverages. Specimens should be adequately separated and identified to avoid mix ups.
5. Investigational products should be stored in a manner to prevent mix ups and access should be limited only to delegated study personnel. Drug accountability logs must be maintained contemporaneously and include record of receipt, dispense/return by subject and the final disposition including destruction records.

There were no refusals and no samples collected. The Investigator was informed of his responsibility to adhere to the regulations promulgated by the FD & C Act with regards to clinical research and of the legal and administrative sanctions available to FDA for failure to do so.

Post-Inspectional information and FMD 145 should be sent to:
Danish A. Jabbar, M.D.
1153 E. Gannon Dr.
Festus, MO 63028

Recommended follow up NAI. Refer to CDER reviewer for final classification and re-inspection date.

O: KAN-DO files, and electronically in OSAR.
Notified Ryan.Raffaelli@fda.hhs.gov, CDER-BIMO-ForCause-EIR@fda.hhs.gov and Joseph.peacock@fda.hhs.gov, EIR package should be available in OSAR within 48-72 hours.

Products Covered

Product Code	Establishment Type	Description	Additional Product Description
60 L I P 09	Clinical Investigator/Animal Clinical Investigator	Buprenorphine HCl (Analgesic)	buprenorphine injection

Inspected Processes & District Decisions

PAC	Establishment Type	Process Code	Inspection Conclusions
48811F	Clinical Investigator/Animal Clinical Investigator	60 L I P	No Action Indicated

Final Decision	District Decision Made By	District Decision Date/Time	Decision Type	Follow-Up
N	Olenjack, Dawn	01/30/2018 01:57 PM	No Action Indicated	

Remarks

PAC	Establishment Type	Process Code	Inspection Conclusions
48811F	Clinical Investigator/Animal Clinical Investigator	60 L I P	No Action Indicated

Final Decision	District Decision Made By	District Decision Date/Time	Decision Type	Follow-Up
N	Hammond, Deborah	02/04/2018 03:43 PM	No Action Indicated	

Remarks

Refer to Ryan Raffaelli, CDER for review, final classification, and re-inspection.

Refusals

No refusal

Related Operations

Samples Collected	Recall Numbers	Related Complaints
		7311

FDA 483 Issued? No

Assignees Accomplishment Hours

Employee Name	Position Class	Hours Credited To	PAC	Establishment Type	Process	Hours
Olenjack, Dawn	Investigator	BIMOW	48811F	Clinical Investigator/Animal Clinical Investigator	60 L I P	39
Total Hours:						**39**

Endorsement Details

Endorsing Supervisor Name
Hammond, Deborah

Date and Time of Signature
02/04/2018, 16:05:11 EST

Investigator Name

Date and Time of Signature

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SUMMARY

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Dr. Danish A. Jabbar has no inspectional history with FDA. The current inspection covered protocols:

HS-16-555: *A Phase III, Randomized, Double-Blind, Placebo-Controlled, Enriched-Enrollment Withdrawal, Multicenter Study to Evaluate the Efficacy and Safety of a Long-Acting Subcutaneous*

Injectable Depot of Buprenorphine (CAM2038) in Subjects with Moderate to Severe Chronic Low Back Pain Currently Treated with Daily Opioids sponsored by Braeburn Pharmaceuticals, 47 Hulfish Street, Suite 441, Princeton, New Jersey.

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2. Dr. Jabbar is responsible for assuring duties are delegated to individuals with appropriate training and education to perform them.
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There were no refusals. I informed Dr. Jabbar of his responsibility to adhere to the regulations promulgated by the FD & C Act with regards to clinical research and of the legal and administrative sanctions available to FDA for failure to do so.

ADMINISTRATIVE DATA

Inspected firm:	Danish A. Jabbar, M.D.
Location:	1153 E Gannon Dr Festus, MO 63028-2611
Phone:	636-282-0380
FAX:	314-747-8693
Mailing address:	1153 E Gannon Dr

	Festus, MO 63028-2611
Dates of inspection:	1/2/2018-1/3/2018, 1/9/2018, 1/23/2018
Days in the facility:	4
Participants:	**Dawn C Olenjack, Investigator**

On 12/29/17, I spoke with Jennifer A. Johnson who identified herself as the Practice Manager and the person responsible for research with Dr. Jabbar. I informed her I would be starting an inspection on 1/2/18 but disclosed no study specific information. She informed me they only conduct research visits on Tuesdays and Wednesdays at 1153 E. Gannon Dr., Festus, MO 63028. She stated they maintain all study records at that address.

On 1/2/18, I presented my credentials and issued the FDA 482 Notice of Inspection to Danish A. Jabbar, M.D., Principle Investigator.

I closed the inspection on 1/3/18 with no FDA 483 issued. On 1/9/18, I returned to collect additional records and issued the FDA 482 to Jennifer A. Johnson, Practice Manager. She stated Dr. Jabbar was out of the country and would not return to the office until 1/23/18. Therefore, I left the inspection open until I could speak with him regarding the discrepancies I observed with signatures on FDA 1572s, financial disclosures and clinical trial agreements.

On 1/23/18, I issued an FDA 482 to Danish A. Jabbar. (Note: I wrote the time of issue as 12:30 a.m. when it should have been written as p.m.) Dr. Jabbar informed me of the documents he signed and identified those signed by someone else in his name. He signed an Affidavit (**Attachment 5**) explaining the circumstances under which he believed prior business associates were responsible for signing his name to study records.

HISTORY

There was no inspectional history for Danish A. Jabbar, M.D. He is a licensed physician, Board Certified in Internal Medicine. His solo private practice is Midwest Medical Practitioners located at 525 Jeffco, Blvd., Arnold, MO 63010. A copy of his current CV is included as **Exhibit 1**. A list of his FDA regulated trials is included as **Exhibit 2**. Dr. Jabbar confirmed he had not enrolled any subjects in the trials listed because he only had screen fails and withdrawals to date. The records I reviewed, confirmed his statement.

Dr. Jabbar stated he conducts clinical research under the business name Amicis Clinical Trials which he formed in May of 2017 after dissolving his relationship with Bracket Trials, LLC in March 2017. In this report, the two business entities will be referred to as Amicis and Bracket.

Research clinic hours are Tuesdays and Wednesdays 9:00am- 5:00pm.

FMD 145 AND OFFICIAL CORRESPONDENCE

All correspondence shall be directed to Dr. Jabbar at the mailing address in the administrative section of this report.

INTERSTATE (I.S.) COMMERCE/ JURISDICTION

All investigational products (IPs) for protocol HS-16-555 in support of IND# 127493 and protocol# CCD-05993A3-01 for IND# 133679 were shipped to the site in interstate commerce.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

Dr. Danish A. Jabbar, Principal Investigator informed me he was responsible for all clinical trial conduct including but not limited to regulatory and subject records; subject screening, evaluation and treatment; IP storage and disposition; protocol adherence and Adverse Event evaluation and management.

Jennifer A. Johnson, Practice Manager and Clinical Research Coordinator (CRC) stated she has worked as a medical assistant for Dr. Jabbar since November 2016. She stated she was not the primary CRC until after Dr. Jabbar formed Amicis. She stated she was trained on the HS-16-555 protocol, but stated Mr. Harbeer Singh was the primary and she did not really work on the trial. She informed me for the CCD-05993A3-01 trial she is responsible for IRB and regulatory information; completing case records; performing pulmonary function tests (PFTs); obtaining informed consent; IP receipt, storage and temperature monitoring and for drawing, processing and shipping laboratory samples.

AUTHORITY AND ADMINISTRATION

HS-16-555 Protocol:

On 1/2/18, Dr. Jabbar stated he conducts all clinical research his clinic at the 1153 E. Gannon under the business name Amicis Clinical Trials. Dr. Jabbar stated prior to creating Amicis, he chose to partner with Sami Anwar and form Bracket Trials, LLC in order to gain experience in conducting clinical research. Dr. Jabbar explained Mr. Anwar is located in Richland, Washington and has a medical degree from Pakistan, but is not licensed in the US. Therefore, Mr. Anwar forms partnerships with physicians to have them act as Principal Investigators (PIs) and conduct trials under the partnership's business name (ie. Bracket Trials, LLC), while Mr. Anwar maintains the study records and agreements with sponsors.

On 1/23/18, Dr. Jabbar informed me that sometime in 2016, at a dinner hosted by a colleague, Mr. Anwar solicited him to form a partnership in which Dr. Jabbar would serve as the Principal Investigator on clinical trials. He stated he observed Mr. Anwar soliciting other physicians at that party. Dr. Jabbar explained he was new to research and Mr. Anwar promised access to sponsors and studies as well as training and assistance with all clinical trial conduct.

Dr. Jabbar informed me some time after he met Mr. Anwar, he visited his research facility (Zain Research) located at 2630 N. Columbia Center Blvd, in Richland, Washington and was impressed by the organization and set up. He stated he verbally agreed to the partnership but did not sign the written contact provided by Mr. Anwar. Dr. Jabbar further stated he was not permitted to review; and he did not sign any FDA 1572 forms, CVs, Clinical Trial Agreements or Financial Disclosure statements while with Bracket. He said Mr. Anwar and/or his employees at Bracket generated and maintained all regulatory records for the studies. He stated Mr. Anwar, or one of his employees, would bring the records from Washington to his site when monitoring visits were scheduled and then take them back when they left.

Dr. Jabbar stated sometime after Subject 001 was screened for the Braeburn trial on 2/8/17, he noticed a CV with his name on it that did not accurately reflect his research experience and it was not his signature on the document. He stated he was already concerned with not seeing the study documents and this elevated his concerns for potential misconduct by Bracket in his name and what it would do to his reputation and medical license. He stated as a result, in March 2017, he informed Mr. Anwar that he wished to dissolve their business relationship.

Dr. Jabbar informed me the split with Bracket was not amicable and that Mr. Anwar refused to provide him with any of study related documents they had maintained prior to the split. Dr. Jabbar explained Mr. Anwar's refusal to allow him to review and maintain study related records was one of his issues with Bracket.

Ms. Johnson informed me once Dr. Jabbar formed Amicis; Medpace- the CRO for Braeburn, provided copies of the regulatory records they had received from Bracket, and she put them in the regulatory binders. She and Dr. Jabbar both admitted they didn't review each record in detail. In the regulatory binders for the Braeburn trial, I found records with signatures that did not appear to be made by Dr. Jabbar. On 1/23/18, he confirmed he did not sign the following records:

- CV dated 9/26/16 (**Ex 3**)
- FDA 1572 dated 11/9/16 for the Braeburn HS-16-556 protocol under Bracket (**Ex 4**)
- Bracket/Braeburn Clinical Trial Agreement dated 11/8/16 (**Ex 5**)
- Financial Disclosure Questionnaire for the Braeburn Trial under Bracket dated 11/9/16 (**Ex 6**)

I asked him if knew who signed his name on these records to which he answered: "I do not recognize this signature. The paperwork was done on my behalf. I was told the paperwork would be taken care of by Mr. Anwar." Dr. Jabbar stated his signature is very distinct. He confirmed he generated and signed the following records:

- HS-16-555 protocol Site Delegation Log for Amicis (**Ex 7**)
- CV dated 8/17/17 (**Ex 1**)
- Amicis FDA 1572 for the Amicis/Braeburn study dated 7/30/17 (**Ex 8**)
- Amicis/Braeburn Clinical Trial Agreement dated 6/29/17 (**Ex 9**)

See the affidavit (**Attachment 5**) for more details.

Training was provided to study personnel at the SIV meeting on 11/17/16. It is unclear how duties were initially delegated without the initial Delegation Log. Once Dr. Jabbar resumed the trial in July 2017, it appears he appropriately delegated responsibilities for study conduct while retaining control and knowledge of the study. He stated he recruited primarily from his own patients. He said while with Bracket, they did sent IRB approved letters to local physicians.

Dr. Jabbar told me he stopped all recruiting after Subject 070-001 because of is concerns about the records being handled by Mr. Anwar and his employees. He explained he waited until he had IRB approval and all of the regulatory requirements completed under his new business, Amicis before he screened any more subjects. He screened Subject 070-002 on 8/16/17 and Subject 070-003 on 8/23/17. Subject 070-002 was lost to follow up after failing to return for the visit after screening. Subject 070-003 was failed for positive Hepatitis C antibody with RNA detected.

Dr. Jabbar stated they had difficulty recruiting more subjects and therefore they were terminated by the sponsor and the site closeout visit was on 12/20/17 (**Exhibit 10**).

Central lab for HS-16-55 protocol:

Medpace Laboratories
5365 Medpace Way
Cincinnati, OH 45200

Protocol CCD-05993AA3-01:

Dr. Jabbar informed me initiated this Chiesi sponsored protocol after leaving Bracket and that he can attest he was responsible for generating and signing all records for that study. A copy of the Clinical Trial Agreement is included as **Exhibit 11.**

Dr. Jabbar and Ms. Johnson both informed me the Chiesi asthma protocol # CCD-05993AA3-01 was their only active study, but they had not successfully enrolled subjects yet due to the narrow eligibility requirements. Ms. Johnson provided me the study binders and I observed they had consented and screened 10 subjects all of which failed screening. **Exhibit 12** is a copy of the initial and most recent FDA 1572s for protocol # CCD-05993AA3-01 signed 4/23/17 and 10/6/17 respectively. On 1/23/18, Dr. Jabbar confirmed it is his signature on these 1572 forms.

See the IRB section for all approval dates for the protocols reviewed during this inspection.

PROTOCOLS

HS-16-555

The sponsor closed this site officially on 12/20/17 for lack of enrollment. I reviewed all available records for this study. See the General Discussion with Management section of this report for details.

CCD-05993AA3-01

At the request of Ryan Raffaelli, CDER reviewer, I verified the site obtained appropriate IRB approvals, informed consent and followed the protocol for the 10 screen failures. No subjects had enrolled or received IP as of 1/9/18. The records I reviewed were complete and in good order.

INSTITUTIONAL REVIEW BOARD

Braeburn HS-16-555 protocol

The Institutional Review Board (IRB) was:
Copernicus Group IRB
5000 Centre Green Way, Suite 200
Cary, NC 27513

The study was initially approved on 11/16/16 under protocol v.5 dated 9/1/16 and Informed Consent Form (ICF) version 3 for Bracket Trials, LLC. The approval letter is included as **Exhibit 13.** I did not collect copies of the protocol as the site was closed without enrollment. Protocol version 8 was included in the background materials for this assignment. **Exhibit 14** is a copy of ICF v.6, the most recent version used, signed by Subject 070-002 with initials RD on 8/16/17.

I observed the site obtained IRB approval and informed consent prior to initiating screening related activities. Continuing review was approved on 5/15/17 which included protocol v.8 and ICF v.6. They had not maintained copies of each protocol and ICF version after initial approval, but were able to get copies during the inspection.

The site close out visit was held 12/20/17. The site did not have an IRB letter acknowledging site closure on 12/20/17. Ms. Johnson stated she did not realize she needed to notify them. She provided me confirmation she notified the IRB on 1/3/18.

Chiesi CCD-05993AA3-01protocol

The Institutional Review Board (IRB) was:
Chesapeake IRB
6940 Columbia Gateway Dr., Suite 110
Columbia, MD 21046

This study was still open to enrollment. The study was initially approved on 7/21/17 under protocol v.2 dated 5/19/17 and Informed Consent Form (ICF) version 5/17/17 for Amicis Clinical Trials. LLC. The approval letter is included as **Exhibit 15.** Protocol version 3 dated 10/19/17 was approved on 10/27/17 and currently in effect. I did not collect copies of the protocol as the site had not enrolled any subjects to review for protocol adherence.

I observed the site obtained IRB approval and informed consent prior to initiating screening related activities. A copy of the most recent version of the ICF (dated 5/17/17 and revised 8/16/17) signed by Subject 129-010 -LH is included as **Exhibit 16.**

HUMAN SUBJECT RECORDS

Dr. Jabbar stated he delegated the duty of obtaining written informed consent to his study coordinators after he discussed the studies and answered all questions from his patients. Subjects are provided a copy of their signed ICF. Dr. Jabbar informed me the subjects were allowed unlimited time to read over the consent and ask questions.

Source records were paper and organized in binders by subject. I conducted a 100% review of Subject Informed Consent Forms for both studies and found no significant discrepancies. It appeared that all subjects signed and dated their own consent forms.

Braeburn HS-16-555 protocol

This was site 070. Three subjects were screened. As previously described, no subjects were enrolled. The site had not maintained a screening enrollment log while the study was active. They did create a Master Subject Log at the close out visit on 12/20/17 (**Exhibit 17**). There was no Delegation log when the study started under Bracket. I was unable to verify duties were appropriately delegated to Sub-Investigator Sami Anwar considering he is not a licensed physician. Dr. Jabbar explained that Mr. Anwar assigned himself as Sub-Investigator, but did not see any study subjects. The delegation log for Amicis was made at the close out visit and not when they assumed the study (**Exhibit 7**).

I reviewed all screening records. I observed missing screening laboratory reports in the study files for Subject 070-001 and 070-003, but Ms. Johnson was able to get copies from Medpace. All pages of the questionnaires were not identified by the Subject ID and date of completion. Dr. Jabbar

showed me each subject's medical history in his electronic medical record system (EMR by Practice Fusion). I verified their histories met eligibility requirements.

Chiesi CCD-05993AA3-01 protocol

I verified the 10 subjects screened to date were appropriately failed due to eligibility requirements. A copy of the screening log is included as **Exhibit 18**. On the Delegation log **(Exhibit 19)** study coordinators are allowed responsibility for reviewing and signing source documents and the electronic case records (eCRFs). Ms. Johnson explained she didn't realize he Principal Investigator must make the final review and sign off on the records. She stated she thought it was part of completing the records.

FINANCIAL DISCLOSURE

As reported previously, the only Financial Disclosure record on file for the Braeburn study was not signed by Dr. Jabbar. The sponsor did not request an additional disclosure after the split with Bracket.

I verified Dr. Jabbar signed a financial disclosure for the Chiesi protocol reporting no interests (**Ex. 20**).

ELECTRONIC RECORDS AND ELECTRONIC SIGNATURES

The source records for both studies were primarily paper. I did not review the electronic systems as there had been no enrollment for either study. Sponsor and monitoring communications were primarily through e-mail.

TEST ARTICLE ACCOUNTABILITY

There was an ambient temperature, locked cabinet for drug storage in an unlocked room utilized by study and non-study personnel. A min/max thermometer was utilized and temperature monitoring logs were available for the time the IP was stored for the HS-16-555 protocol. I did not review the IP accountability for the *CCD-05993AA3-01,* but observed the IP was stored in this cabinet. Ms. Johnson and Dr. Jabbar both stated only he had the keys to the cabinet. The cabinet was not dedicated to investigational products and contained sample medications for use in his primary practice without distinct separation and identification of the investigational product. I discussed the need for dedicated, secure IP storage under the appropriate storage conditions. In addition, they must store scheduled drugs according to DEA requirements.

I reviewed the accountability records for the HS-16-555 protocol and found they had not been maintained contemporaneously. I was able to verify all IP received was accounted for at the close out visit on 12/20/17. No IP was dispensed and all had been returned to Medpace.

RECORDS CUSTODY AND RETENTION

Paper and electronic records were available and provided to me upon request but all records had not been retained as described throughout this report. Dr. Jabbar and Ms. Johnson both expressed they were not fully aware of the record retention requirements for clinical research. However, during the inspection, they made every effort to retrieve all e-mail correspondence and obtain missing records for the Braeburn study by asking Medpace to provide copies. Ms. Johnson also began reviewing the regulatory binders for the Chiesi trial during the inspection, to ensure all necessary records and correspondence were on file.

REPORTS TO SPONSOR

No subjects were enrolled in the Braeburn or Chiesi studies. No reports were due.

MONITORING

Braeburn HS-16-555 protocol:

The sponsor contracted monitoring duties to Medpace of Cincinnati, OH. The original monitoring log was one of the records retained by Bracket. I observed from the Bracket Site Initiation Visit (SIV) report (**Exhibit 21**), the visit occurred on 11/17/16. On page 6 of this exhibit under recruitment strategies, Ms. Lena Al-Rashed, CRA for Medpace, reported: "Sub-I, S. Anwar, stated that from their database of about 26,000 patients, the site has approximately 18200 patients (70%) currently being treated with 80mg/day or more of morphine or MED. Site staff estimate that about 5,000 of these patients could be potentially eligible for enrollment. S. Anwar explained that he and H. Singh, CRC, will pre-screen by looking through patient charts for patients currently scheduled to come into the clinic in the coming weeks. ***" and "Sub-I, S. Anwar, indicated that he and CRC, H. Singh will be the primary staff member responsible for recruitment. He anticipates spending about 30 minutes per day identifying patients and reviewing incoming charts. Once patients are identified, they are passed along to the PI, D. Jabbar, for further review and approval for screening."

On 1/23/18, I asked Dr. Jabbar about the claims. He explained he hadn't realized there was a SIV report as it was originally sent to Bracket and not shared with him. Ms. Johnson and Dr. Jabbar acknowledged that once they re-started as Amicis, she just filed most of the records they received from Medpace; so neither of them had read the report prior to my asking about it. Ms. Johnson had informed me on 1/9/18, they had approximately 750 patients at the time of the SIV in November 2016 and that currently they have 1500-1800.

Dr. Jabbar also confirmed the numbers claimed by Mr. Anwar were not accurate. He further stated he had nowhere near that volume of patients and that only a small fraction of his patients are on controlled substances for pain because he is not a Pain Management Practice. He then stated he believed Mr. Anwar was "trying to over-showcase our site in order to get the study". Dr. Jabbar also disputed the claim that Mr. Singh and Mr. Anwar conducted recruiting efforts, stating he alone identified and approached his patients that were potentially eligible.

In the same SIV report (**Exhibit 21, page 8**) under Maintenance of source documentation, Ms. Al-Rashed reported "The Sub-I, S. Anwar, informed the CRA that he and the primary CRC, H. Singh, will be responsible for the maintenance and completion of all source documents. ***" I observed Mr. Anwar signed the Site Source Document Process Form on 11/17/16 (**Exhibit 22**).

Dr. Jabbar confirmed Mr. Anwar handled all study documentation with the exception of subject visits which he stated he or Mr. Singh completed.

The Amicis SIV visit occurred on 7/28/17. There were no interim visits. The site close out visit was on 12/20/17. A copy of the monitoring log is included as **Exhibit 23**.

Chiesi CCD-05993AA3-01 protocol

Monitoring was contracted to CROMSOURCE, Inc. of Waltham, MA. The SIV occurred on 8/17/17 and there had been interim visits on 9/27/17 and 11/21/17. A copy of the log is in **Exhibit 24**.

COMPLAINTS<REDACT>

This section and any reference to it should be redacted from the FDM 145. Please see the Investigative Memorandum of Assignment dated 1/24/18 for details specific to the CDER- for-cause memorandum of assignment questions regarding anonymous OSI complaint # 7311.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

No FDA 483 was issued.

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

An initial close out meeting was held 1/3/18 with Dr. Jabbar and Jennifer Johnson. I advised them of the administrative and legal actions available to FDA should they fail to adhere to the regulations promulgated by the FD & C Act or other statutes. I provided them information on where to find guidance documents on fda.gov and made them aware there are industry resources as well. The following general items were discussed as observed during the inspection and at the close out meeting on 1/3/18:

1. They are responsible for utilizing Good Documentation Practices and assuring their records are accurate, complete and maintained in an accessible format for the required time. Subject ID numbers should be utilized on all paper and electronic study generated records. All study related correspondence shall be retained for each study. Leaving correspondence and attachments in e-mail accounts does not ensure they are available for required time period.
2. Dr. Jabbar is responsible for assuring duties are delegated to individuals with appropriate training and education to perform them.
3. They should keep records regarding calibration and maintenance of refrigerators, freezers and the thermometers used to monitor temperatures.
4. Specimen refrigerators and freezers should be free from food and beverages. I observed cans of soda in the specimen refrigerator on 1/2/18. No specimens were stored at the time. Specimens should be adequately separated and identified to avoid mix ups.
5. Investigational products should be stored in a manner to prevent mix ups and access should be limited only to delegated study personnel. Drug accountability logs must be maintained contemporaneously and include record of receipt, dispense/return by subject and the final disposition including destruction records.

No additional discussion items resulted from my re-opening the inspection on 1/9/18. At the final closeout on 1/23/18, I reviewed the discussion items again. I reminded Dr. Jabbar and Ms. Johnson of the legal and administrative sanctions available to FDA should they fail to adhere to the regulations promulgated by the FD & C Act with regards to clinical research. Dr. Jabbar thanked me and stated he is pleased to have learned from the inspection. He committed to adhering to the regulations with the Chiesi trial and future studies and to seek more clinical research training for himself and Ms. Johnson.

EXHIBITS COLLECTED

1 ex 1 Dr. Jabbar CV 8-17-17, 5 pages
2 ex 2 Study List, 1 page
3 ex 3 Dr. Jabbar CV 9-26-16, 6 pages
4 ex 4 FDA 1572 for HS-16-555 dated 11-9-16, 2 pages
5 ex 5 Bracket CTA dated 11-8-16, 5 pages
6 ex 6 Dr. Jabbar HS-16-555 FD under Bracket dated 11-9-16, 1 page
7 ex 7 HS-16-555 Delegation log for Amicis, 1 page

8 ex 8 HS-16-555 FDA 1572 for Amicis signed 7-30-17, 2 pages
9 ex 9 HS-16-555 Amicis CTA signed 6-29-17, 36 pages
10 ex 10 emails regarding site closure HS-16-555 protocol, 5 pages
11 ex 11 Chiesi- Amicis CTA signed 7-5-17, 20 pages
12 ex 12 FDA 1572 forms for Chiesi protocol, 6 pages
13 ex 13 Initial IRB approval letter for HS-16-555, 3 pages
14 ex 24 Monitoring visit log for Chiesi protocol, 24 pages
15 ex 15 Initial IRB approval letter for Chiesi protocol, 2 pages
16 ex 16 Signed ICF v17May2017 for Chiesi protocol, 15 pages
17 ex 17 Master Subject Log for HS-16-555 protocol, 1 page
18 ex 18 Screening and Enrollment log for Chiesi protocol, 2 pages
19 ex 19 Delegation log for Chiesi protocol, 1 page
20 ex 20 Dr. Jabbar FD for Chiesi protocol signed 4-23-17, 1 page
21 ex 21 11-17-16 SIV report for HS-16-555, 10 pages
22 ex 22 Site Source Documentation Process form, 1 page
23 ex 23 Monitoring visit log for HS-16-555, 1 page
24 ex 24 Monitoring visit log for Chiesi protocol, 1 page

ATTACHMENTS

1 FDA 482 issued 02JAN2018, 3 pages
2 FDA 482 issued 09JAN2018, 3 pages
3 FDA 482 issued 23JAN2018, 3 pages
4 Assignment memo 26SEP2017, 8 pages
5 Dr Danish Jabbar AFFIDAVIT, 4 pages

Dawn C.
X Olenjack -S

Digitally signed by Dawn C. Olenjack -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000367167, cn=Dawn C. Olenjack -S
Date: 2018.01.30 15:02:08 -06'00'

U.S. FOOD & DRUG ADMINISTRATION

Inspection Assignment Memorandum

User Fee: Yes (PDUFA)
Surveillance: No
Directed: Yes (For Cause – Complaint #7311)

Application: Yes (IND)
Submission: Premarket

Entity: Clinical Investigator

Date: 09/26/2017
From: Ryan Raffaelli, M.D.
Good Clinical Practice Compliance Oversight Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations, CDER
Ryan.Raffaelli@fda.hhs.gov

To: ORAHQ BIMO Inspection POC (BIMOW)

Preannounce: Yes
Priority: High (90 days)
ORA Due Date: 12/25/2017

Compliance Program Guidance Manual Number: 7348.811
Program Assignment Code: 48811F
Operation Code: 12 (Domestic)

Application/File Number: IND 127493
Product Name: Buprenorphine (CAM2038)

IND 127493:
Sponsor: Braeburn Pharmaceuticals (Braeburn)
Protocol Number: HS-16-555

Center Participation: No
Joint Regulatory Agency Participation: No

Establishment(s) for inspection	**FEI Number**	**FACTS Number**
Danish Jabbar, M.D. 1153 E. Gannon Dr. Festus, MO 63028	3013856747	11775628
Inspection History	None	

Note	**Please contact Center Reviewer, Ryan Raffaelli, at 301-796-2376 prior to the beginning of the inspection to verify the focus and intent of the inspection. If the Reviewer is unavailable, please contact Rachel Skeete at 301-796-5341.** We frequently receive real-time information from the review team that may change the focus of the inspection. Please follow the compliance program with emphasis on the specific instructions in the memorandum. If significant deviations are found during the inspection that may have impact on the safety of study subjects or accuracy and reliability of the data, we request that you contact me immediately to discuss expanding the scope of your inspection. At the end of the inspection, send an e-mail to ryan.raffaelli@fda.hhs.gov with any inspection summary of findings. If a form FDA-483 is issued, e-mail or fax it to my attention at 301-847-8748. **Forward the EIR and exhibits to the Center contacts listed in Section IV below.** **Important:** Forward any post-inspection correspondence from the establishment as soon as possible. All post-inspection correspondence must be reviewed prior to issuing any post-inspection notification of compliance status.

Additional Notes:

We prefer that you announce the inspection no more than a few business days ahead of time, and we defer to ORA if you wish to conduct the inspection unannounced.

If at any time during the inspection it appears that the violations may warrant an Official Action Indicated (OAI) classification, please contact the Center Reviewer immediately.

If significant deviations are revealed during the inspection that may affect the safety of study subjects and/or the accuracy and reliability of the data, we request that you **contact Headquarters immediately** to discuss whether the inspection should be expanded.

Important: Please see Section IV below for "Instructions at the Completion of the Inspection."

I. Background Information

OSI received a complaint regarding Dr. Danish Jabbar's conduct as clinical investigator (CI) of the following protocol under IND 127493:

- Protocol HS-16-555, "A Phase III, Randomized, Double-Blind, Placebo-Controlled, Enriched-Enrollment Withdrawal, Multicenter Study to Evaluate the Efficacy and Safety of a Long-Acting Subcutaneous Injectable Depot of

Buprenorphine (CAM2038) in Subjects with Moderate to Severe Chronic Low Back Pain Currently Treated with Daily Opioids"

The complainant, who requests to remain anonymous, is employed by the CI and reports several concerns with regard to Dr. Jabbar's conduct of this study, and possibly others[1].

Specifically, the complainant alleged the following:

- Falsification of 1) data, 2) study records and 3) qualifications to conduct clinical trials
    - The complainant alleges the CI enrolls subjects into the study and states that he sees them, even though they never visit the office. The complainant also alleges that the subjects are not aware they are being enrolled in the study (See Section II. for specific instructions regarding the alleged falsification.)
- Prior accusations of the CI attempting to falsify data by a site management organization that terminated its contract with the CI
- Lacking and falsifying records to support adequate investigational product (IP) storage, handling and accountability for scheduled drugs (opioids – hydrocodone and morphine)

Note: OCI has also opened an investigation.

See Background Materials for additional details and Inspection Instructions below.

II. Specific Inspection Instructions

1. Please review an adequate number of study subject records, at least ⅓ to ½ of the total number of subjects. If the total is less than 25 subjects (that appears to be the case), please review all records, if feasible.

Please pay special attention to the following numbered instructions and submit relevant documentation to support any regulatory violations:

[1] Another "protocol" in the complaint was identified as CHF-718-PMDI under IND 133679. However, that "protocol identifier" is simply the investigational product, CHF-718, in a formulation dispensed by a pressurized Metered Dose Inhaler (pMDI). The complainant states that Dr. Jabbar has been recently approved to participate in two new, though unidentified, studies as CI. We do not know if his participation may be in an investigation of the drug CHF-718. If the CI is conducting a CHF-718 pMDI study, that study could be another study for inspection, if the inspection is expanded.

2. Obtain a list of all trials conducted by the CI. On this list, please note (a) the IND number for each study; (b) the sponsor of each study; and (c) the Institutional Review Board (IRB) providing oversight for each study.
3. Expand your inspection, as needed, to include an audit of one other trial that was conducted under an IND (see footnote[1]), to determine the CI's general compliance with applicable regulations. If the inspection is expanded, please try to focus on a Phase 3 trial with a study design that includes blinding and randomization. If possible, inspection of a recent trial (conducted in the past two years) with high enrollment is preferred. If you feel that further expansion is warranted, please contact Headquarters and obtain Headquarters' concurrence before expanding the inspection.
4. **Review the records associated with the trial referenced above, and verify and document the complainant's allegations. Please pay special attention to the following:**
    a. Adequacy of the CI's oversight of the study
    b. Evidence of fabrication or falsification of documents
        i. Please see instruction #5 if fabrication or falsification is found.
        ii. Determine whether there is evidence that the CI is fabricating subjects and subject records (complainant alleges subjects are enrolled in name only)
        iii. Review source documentation, including requisition forms, of laboratory data, and assess for potential lack of anticipated variation in lab findings across subjects (complainant alleges that CI draws his own blood to submit as subject data)
        iv. Review source documentation regarding subjects' medical diagnoses to determine subject eligibility (complainant alleges CI falsifies subject records to meet desired enrollment thresholds)
        v. Determine whether there is evidence that the details of the CI's curriculum vitae and prior research experience have been fabricated or falsified (complainant alleges fabrication and reports that a sponsor had ended a contract due to lack of evidence of actual CI experience)
    c. Documentation of investigational product (IP) storage, handling and accountability as per the protocol and as required for controlled substances
        i. Complainant alleges that CI does not have the proper equipment (locked cabinet, temperature monitoring) to store IPs that are controlled substances in compliance with the protocol or applicable regulations.
        ii. Complainant alleges that CI falsifies storage temperature logs.

d. Informed consent process to determine whether subjects received informed consent and if documentation of informed consent (as required by our regulations and the protocol) was adequate and verifiable (complainant alleges CI fabricated signatures)
e. Enrollment of ineligible subjects, that is, those who did not meet the inclusion criteria or who met exclusion criteria

5. **If falsification is found, determine the CI's role in carrying out or uncovering the falsification. Collect any available evidence to show that the CI submitted falsified information to the FDA or to the sponsor and document your findings in the EIR. If possible, also obtain affidavits from all parties involved. Please pay special attention to the following:**
    a. What types of documents were falsified?
    b. How were the documents falsified?
    c. Is there evidence to suggest that the falsification was limited to any specific:
        i. Type of record?
        ii. Individual subject's records?
        iii. Individual study?
        iv. Date or period of time?
    d. If the CI indicates that the falsification was done by someone other than him/herself:
        i. When did the CI become aware of the falsification?
        ii. How did the CI become aware of the falsification?
        iii. What is the CI's evidence that a third party falsified records or data?
        iv. Did the CI report the falsification to the sponsor or to FDA?
            1. If reported, was report prompted by the sponsor/ monitor/ IRB, or did the CI submit the report on his/her own initiative?
        v. How many other studies, if any, was the third party, who allegedly fabricated records/data, involved in under the CI?
        vi. Did the CI investigate to determine the scope of the falsification?
            1. If so, what did the CI's investigation consist of?
                a. What did the CI review?
                b. How did the CI verify the presence or absence of falsification?
            2. Were all of the trials that the third party was involved in evaluated to determine whether there was any falsification in the other trials?

6. OSI is providing as background materials a copy of Protocol HS-16-555 obtained from the IND files. However, OSI does not know whether the CI used this version of the protocol in conducting the trial. Please obtain a copy of the following documents and include in the EIR:
   a. The relevant protocol(s) in effect when trial subjects initially began enrollment
   b. All protocol amendments in effect at the site while the trial is/was ongoing
   c. All protocol appendices
   d. All protocol-specific manuals and any other protocol-specific materials and instructions provided by the sponsor as part of the investigational plan (for example, a protocol-specific newsletter communicating additional trial requirements that may not be mentioned in the protocol)
   e. All versions of the informed consent documents (NOT a copy of each individual subject's consent document)
   f. All IRB approval notices that informed the site when the protocol amendments, if any, were approved

III. General Inspection Instructions

1. Please document in the EIR which study records were reviewed during the inspection.
2. **If you find there are missing records for any specific subject**:
   a. Please review all available records for that subject and document in the EIR:
      i. That you reviewed all available records for the subject(s) in question
      ii. What study records are missing for the specific subject(s)
   b. DO NOT rely solely on "Notes to File" or third party reports (that is, sponsor, monitoring, or IRB reports) as evidence of missing records or that certain study procedures were not conducted.
3. Submit a copy of any screening and enrollment logs with subject identification (ID), and confirm on-site that the number of subjects on these logs reflects accurately the number of subjects screened/enrolled. Screening and enrollment logs are commonly used but are not a regulatory requirement. If the site did not use screening/enrollment logs for any inspected studies, please document this fact in the EIR.
4. Submit a copy of any drug accountability records that contain dates, quantities, and use by subjects.

IV. Instructions at the Completion of the Inspection

1. Please e-mail a copy of the following documents to Ryan Raffaelli (ryan.raffaelli@fda.hhs.gov) as soon as they are available:
   a. Form(s) FDA 483
   b. Response(s) to the Form(s) FDA 483
2. **Remind the inspected entity of the 15-business-day time frame for submission of a written response to the observations listed on the Form FDA 483.**
3. **In addition to the ORA procedures for written responses to be sent to the Districts, please request that the inspected entity send a copy of their written response directly to OSI at the address provided below. Also, please forward any written response you may receive as soon as it is available.**
4. **Please submit your EIR and accompanying exhibits to OSI in an electronic format, if possible, with EIR sections and exhibits bookmarked. In addition to bookmarking the exhibits, we would appreciate it if, under the supporting evidence section of each EIR Observation discussion item, you could insert hyperlinks between the referenced exhibits (including the relevant page number) and the pertinent discussion items.** Please return with your EIR a copy of the version(s) of the relevant protocol(s) and consent form(s). EIRs, copies of any written responses, and investigation memoranda should be sent to:

CDER-BIMO-ForCause-EIR@fda.hhs.gov

Paper copies of EIRs, any written responses, and investigation memoranda should be sent to:

Joseph Peacock
Program Analyst
Office of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
Building 51, Room 5320
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone: 301-796-3401

Please notify Joseph Peacock, preferably by email at Joseph.Peacock@fda.hhs.gov, when the EIR is uploaded into OSAR.

5. **E-mail the following information to the OSI reviewer named at the beginning of this assignment as soon as possible, and include this information in the EIR:**

Number of subjects screened	
Number of subjects enrolled	
Number of subjects who completed the study	
Number of subjects who discontinued, with reason(s) for discontinuation	
Number of subjects lost to follow-up	
Number of serious adverse events	
Number of deaths	
Number of subjects whose records were reviewe during the inspection	

V. Background Materials

Background materials are being forwarded electronically and consist of the following:

1. Division of Drug Information email to OSI_Jabbar D
2. Protocol HS-16-555
3. Form FDA 1572_Jabbar D
4. Curriculum vitae_Jabbar D
5. IND list for Dr. Jabbar

CONCUR:

{See electronic signature below}

Rachel Skeete, MD, MHS
Team Leader
Good Clinical Practice Compliance Oversight Branch
Division of Clinical Compliance Evaluation
Office of Scientific Investigations

Electronic Signatures:

Ryan Raffaelli -S
Digitally signed by Ryan Raffaelli -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Ryan Raffaelli -S, 0.9.2342.19200300.100.1.1=2000367255
Date: 2017.09.22 15:34:37 -04'00'

Rachel Skeete -S
Digitally signed by Rachel Skeete -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Rachel Skeete -S, 0.9.2342.19200300.100.1.1=2000371472
Date: 2017.09.22 15:45:00 -04'00'

cc:
OSI Reviewer/Ryan Raffaelli
Branch Chief/Constance Cullity
TL/Rachel Skeete
PHA/Dana Walters
Support Staff/Joseph Peacock

ECMS:/ Cabinets/CDER_OC/OSI/Division of Clinical Compliance Evaluation/GCP Compliance Oversight Branch/Raffaelli, Ryan/Gen complaints - Jabbar, Danish C#7311

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
KANSAS
9050 Marshall Drive Ste 205
Lenexa, KS 66214
(913) 495-5100

TO

2. NAME AND TITLE OF INDIVIDUAL
Danish A. Jabbar, M.D. Principal Investigator

3. DATE
01/02/2018

4. FIRM NAME
Danish A. Jabbar, M.D.

5. HOUR
09:33 a.m.
p.m.

6. NUMBER AND STREET
11 S E. Gannon Dr

7. CITY AND STATE & ZIP CODE
Ft Scott, KS 66728

8. PHONE NO. & AREA CODE
316-387-0310

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www.sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
	Dawn C. Olenjack, Investigator

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(i)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (i)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation

(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
KANSAS
8550 Marshall Dr Ste 205
Lenexa, KS 66214
913 495-4200

TO

2. NAME AND TITLE OF INDIVIDUAL
Jennifer A. Johnson, Practice Manager

3. DATE
01/09/20X8

4. FIRM NAME
Dinish A Ibbar, MD

5. HOUR
09:05 a.m. / p.m.

6. NUMBER AND STREET
1525 Grand Dr

7. CITY AND STATE & ZIP CODE
Pittsburg, KS 66762

8. PHONE NO. & AREA CODE
620-231-0500

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

As a small business that is subject to FDA regulation, you have the right to seek assistance from the U.S. Small Business Administration (SBA). This assistance includes a mechanism to address the enforcement actions of Federal agencies. SBA has a National Ombudsman's Office that receives comments from small businesses about Federal agency enforcement actions. If you wish to comment on the enforcement actions of FDA, CALL (888) 734-3247. The website address is www sba.gov/ombudsman.

FDA has an Office of the Ombudsman that can directly assist small business with complaints or disputes about actions of the FDA. That office can be reached by calling (301) 796-8530 or by email at ombuds@oc.fda.gov.

For industry information, go to www fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
[signature]	Dawn C Olenjack Investigator

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation

(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

1. DISTRICT OFFICE ADDRESS & PHONE NO.
KANSAS
8050 Marshall Dr. Ste 205
Lenexa, KS 66214
(913) 495-5205

TO

2. NAME AND TITLE OF INDIVIDUAL
Dawn A Zeller, MD Regional Investigator

3. DATE
08/23/2016

4. FIRM NAME
Dawn A. Zeller M.D.

5. HOUR
12:30 a.m. / p.m.

6. NUMBER AND STREET
1152 E. Gannon Dr

7. CITY AND STATE & ZIP CODE
E Stds, MO 63028

8. PHONE NO. & AREA CODE
636-219-3300

Notice of Inspection is hereby given pursuant to Section 704(a)(1) of the Federal Food, Drug, and Cosmetics Act [21 U.S.C. 374(a)][1] and/or Part F or G, Title III of the Public Health Service Act [42 U.S.C. 262-264][2]

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For industry information, go to www.fda.gov/oc/industry.

9. SIGNATURE(S) *(Food and Drug Administration Employee(s))*	10. TYPE OR PRINT NAME(S) AND TITLE(S) *(FDA Employee(s))*
	Dawn C. Dlenjack, Investigator

[1] Applicable portions of Section 704 and other Sections of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 374] are quoted below:

Sec. 704(a)(1) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (A) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, tobacco products, or cosmetics in interstate commerce; and (B) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any person (excluding farms and restaurants) who manufactures, processes, packs, transports, distributes, holds, or imports foods, the inspection shall extend to all records and other information described in section 414, when the standard for records inspection under paragraph (1) or (2) of section 414(a) applies, subject to the limitations established in section 414(d). In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products are manufactured, processed, packed, or held, inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, restricted devices, or tobacco products which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act. No inspection authorized by the preceding sentence or by paragraph (3) shall extend to financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this

(Continued on Reverse)

Act), and research data (other than data relating to new drugs, antibiotic drugs, devices, and tobacco products and subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (k), section 519, section 520(g), or chapter IX and data relating to other drugs, devices, or tobacco products, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j)). A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness.

Sec. 704. (a)(2) The provisions of the third sentence of paragraph (1) shall not apply to (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail; (B) practitioners licensed by law to prescribe or administer drugs, or prescribe or use devices, as the case may be, and who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in the course of their professional practice; (C) persons who manufacture, prepare, propagate, compound, or process drugs, or manufacture or process devices solely for use in research, teaching, or chemical analysis and not for sale; (D) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

Sec. 704. (a)(3) An officer or employee making an inspection under paragraph (1) for purposes of enforcing the requirements of section 412 applicable to infant formulas shall be permitted, at all reasonable times, to have access to and to copy and verify any records (A) bearing on whether the infant formula manufactured or held in the facility inspected meets the requirements of section 412, or (B) required to be maintained under section 412.

Sec. 704(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, tobacco product, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

Sec. 704. (c) If the officer or employ ee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

Sec. 704. (d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

Sec. 704(e) Every person required under section 519 or 520(g) to maintain records and every person who is in charge or custody of such records shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and to copy and verify, such records.

Section 704 (f)(1) An accredited person described in paragraph (3) shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

Section 512 (l)(1) In the case of any new animal drug for which an approval of an application filed pursuant to subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, of data relating to experience, including experience with uses authorized under subsection (a)(4)(A), and other data or information, received or otherwise obtained by such applicant with respect to such drug, or with respect to animal feeds bearing or containing such drug, as the Secretary may by general regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination, whether there is or may be ground for invoking subsection (e) or subsection (m)(4) of this section. Such regulation or order shall provide, where the Secretary deems it to be appropriate, for the examination, upon request, by the persons to whom such regulation or order is applicable, of similar information received or otherwise obtained by the Secretary.

(2) Every person required under this subsection to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

[2] Applicable sections of Parts F and G of Title III Public Health Service Act [42 U.S.C. 262-264] are quoted below:

Part F – Licensing – Biological Products and Clinical Laboratories and* * * * * *

Sec. 351(c) "Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation

(Continued on Page 3)

of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Part F – * * * * * *Control of Radiation.

Sec. 360 A (a) "If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e)."

(b) "Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to section 359(a)."

* * * * * *

(f) "The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefore for the purposes of Section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a)."

* * * * * *

Sec. 360 B.(a) It shall be unlawful–

(1) * * *

(2) * * *

(3) "for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required or pursuant to section 360A."

* * * * * *

Part G - Quarantine and Inspection

Sec. 361(a) "The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary."

AFFIDAVIT

SAMPLE NO. n/a

STATE OF: Missouri

COUNTY OF: Jefferson

Before me, Dawn C. Olenjack, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Danish A. Jabbar, MD in the county and state aforesaid, who, being duly sworn, deposes and says:

I am a licensed Medical Doctor, Board Certified in Internal Medicine. I opened my private practice in October 2015 at 525 Jeffco Blvd., Arnold, MO 63010. I met Sami Anwar through a colleague, Nighat Quadri, MD. Mr. Anwar has a Medical degree in Pakistan but is not a licensed medical practitioner in the United States, so he contracts US licensed physicians to serve as Clinical Investigators (CIs) for research studies. He solicited me to form a partnership in which I would serve as the Principal Investigator on clinical trials. I was new to research and Mr. Anwar promised access to sponsors and studies as well as training and assistance with all clinical trial conduct. I visited his research facility located at 2630 N. Columbia Center Blvd, in Richland, Washington and was impressed by the organization and set up. During that visit, I spoke with a Dr. Nand, a PI under Mr. Anwar and he described his duties. That gave me additional confidence, so I verbally agreed to enter an agreement with Sami Anwar to form Bracket Trials, LLC at 1153 E. Gannon, Festus, MO 63028 where we would split income 50%/50% . I rent this space from Dennis Gannon and conduct my research at this address only, not at my Arnold, MO office.

While I was in Washington, Mr. Anwar pushed me to sign a written contract on the spot. I told him I wouldn't sign until I had the chance to read it thoroughly. I never signed the contract but Mr. Anwar proceeded to set up a bank account for Bracket Trials which we both had access. I have since found documentation he set up the tax ID number for Bracket in his name only.

To my knowledge, Mr. Anwar is still located in Richland, Washington. He generated and maintained all regulatory records for the studies I served as the PI. He or one of his employees, would bring the records to my site when monitoring visits were scheduled and then take them back to Washington.

At the time we formed Bracket Trials, LLC, Mr. Harbeer Singh was an employee of Mr. Anwar, but was located in St. Louis, MO. Mr. Singh was assigned to work for me as a Clinical Research Coordinator and Mr. Anwar assigned himself as the Sub-Investigator. He also had the title of Clinical Research Director of Bracket Trials.

Sometime after I screened Subject 001 for protocol HS-16-555, sponsored by Braeburn Pharmaceuticals, I became aware documents were being created in my name without my input. I was

AFFIANT'S SIGNATURE AND TITLE: MD PRINCIPAL INVESTIGATOR

FIRM'S NAME AND ADDRESS (Include ZIP Code): DANISH A JABBAR, MD 1153 E. GANNON DRIVE FESTUS, MO 63028

Subscribed and sworn to before me at St. Louis, Missouri (City and State),

this 23rd day of January, 20 18.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO. n/a

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COUNTY OF: Jefferson

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concerned for my license in that I did not have control over how my name was being used. I called Mr. Anwar sometime in March 2017 and informed him I wanted to dissolve our business agreement. I did not obtain any formal documentation of this discussion. The split was not amicable and Mr. Anwar refused to provide me with copies of study records. Based on his refusal, I do not have all study related records generated by Mr. Anwar and his staff in Washington. After I told him I was dissolving our relationship, he has not physically been in my presence.

In May 2017, I formed my own company, Amicis Clinical Trials. I contracted Mr. Singh to continue as the primary CRC because of his clinical trial experience and knowledge of the protocol. I was able to recover some of the regulatory documents provided by Bracket, to Medpace, the CRO for Braeburn. Investigator Olenjack noted discrepancies and I confirm I never saw or signed the FDA 1572, clinical trial agreement or a financial disclosure questionnaire for the Braeburn trial. That was all done by Bracket.

--The FDA 1572 dated 11/9/16 identifies me as the Principal Investigator, for Bracket, but it is not my signature on the document.

--The Financial Disclosure Questionnaire dated 11/9/16 and a Curriculum Vitae dated 9/26/16 have my name on them, but the signatures are not mine. I did not answer the questionnaire and I did not write the CV. It lists extensive clinical research experience I do not have.

--It appears, Mr. Anwar signed the HS-16-555 clinical trial agreement on 11/8/16. He is listed as the Clinical Research Director of Bracket Trials and I am listed as the Principal Investigator. However, it is not my signature on this agreement.

I had the investigational products, study supplies and training for the Braeburn protocol #HS-16-555 and protocol #CD-001 sponsored by Crestovo. Therefore I contacted the sponsors to discuss my split from Bracket and requested to continue the studies under Amicis. Braeburn agreed to do so. I provided Investigator Olenjack with a copy of my CV that I signed and dated 7/11/17 and an updated one signed 8/17/17; a new FDA 1572 for Amicis signed 7/30/17 and the Amicis/Braeburn clinical trial agreement signed on 6/29/17. I confirm it is my signature on each of those documents.

AFFIANT'S SIGNATURE AND TITLE: Danish Jabbar MD PRINCIPAL INVESTIGATOR

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*: DANISH A. JABBAR, MD 1153 E. GANNON DRIVE FESTUS MO 63028

Subscribed and sworn to before me at St. Louis, Missouri *(City and State)*,

this 23rd day of January, 20 18.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.
n/a

STATE OF
Missouri

COUNTY OF
Jefferson

Before me, Dawn C. Olenjack, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Danish A. Jabbar, MD in the county and state aforesaid, who, being duly sworn, deposes and says:

Crestovo requested an updated CV. I submitted them the CV provided to Investigator Olenjack which I signed 7/11/17. They declined me based on my lack of research experience and chose to keep it with Bracket.

I waited until all regulatory documents were approved in the new business name for the Braeburn study. Mr. Singh consented and screened Subjects 002 and 003 on 8/16/17 and 8/23/17. Subject 002 did not return for the visit after screening and was lost to follow up and Subject 003 was failed due to Hepatitis C.

Investigator Olenjack asked me about statements Mr. Anwar made to Lena Al-Rashad, CRA for Medpace at the site initiation visit on 11/17/16 regarding my site having 26,000 patients in our database in which 70% of them were on 80mg of Morphine or the equivalent. I did not know those statements were made. I was not provided a copy of the SIV report at the time. It was filed with other records from the CRO. I do not have 26,000 patients and although I do prescribe controlled substances for pain, this is not a primary focus of my private practice. I am not a pain management physician. His claims regarding him identifying subjects were also false. I approached my patients and told them about the study. I believe Mr. Anwar was trying to over-showcase our site in order to get the study.

On 8/24/17, I received an e-mail from Ben Fownes, Clinical Research Associate for Medpace, stating they were informed I was under FDA audit and had not reported it to them. I responded 8/25/17 that I, nor any of my employees were under an FDA audit. I also called and told Mr. Fownes that to my knowledge, I was not under FDA audit. I reminded him that due to a study equipment supplier failing to change the site name to Amicis. Bracket was made aware of my continuing the study without them. It was when Mr. Fownes called them to correct it, that someone told him I was under audit and that they should not do business with me. Mr. Fownes acknowledged the accusation was only hearsay and I was allowed to continue as Clinical Investigator. Unfortunately, I was unable to recruit any other subjects and on 10/11/17, Mr. Fownes sent an email informing me that Braeburn was closing my site due to lack of enrollment. The close out visit was on 12/20/17. All Investigational Product was returned.

AFFIANT'S SIGNATURE AND TITLE

Danish A. Jabbar MD PRINCIPAL INVESTIGATOR

FIRM'S NAME AND ADDRESS (Include ZIP Code)

DANISH A. JABBAR MD
1152 E. GANNON DRIVE
FESTUS, MO 63028

Subscribed and sworn to before me at St. Louis, Missouri
(City and State)

this 23rd day of January, 20 18.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.
n/a

STATE OF
Missouri

COUNTY OF
Jefferson

Before me, Dawn C. Olenjack, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Danish A. Jabbar, MD in the county and state aforesaid, who, being duly sworn, deposes and says:

I provided Investigator Olenjack with an e- mail I recovered from my Bracket account. Ms. Tina Schuster erroneously sent the Amicis Contracts to my Bracket email account on 5/17/17. Someone from Bracket answered the email as if they were me, and told her I was no longer interested in conducting the trial and referred her to "my colleague" Candace Green, MD whom I assume is contracted with Mr. Anwar as I do not know her.

I was not fully aware of my responsibilities as a Clinical Investigator. That was the reason I initially partnered with Mr. Anwar. In hindsight, there were red flags. As soon as I was aware of potential misuse of my name, I took actions to dissolve my affiliation with him and Bracket Trials, LLC. I learned from this inspection, that I may need to take further action to ensure my name will not be associated with any business done by Mr. Anwar or Bracket Trials.

I HAVE READ THIS STATEMENT AND IT IS TRUE TO THE BEST OF MY KNOWLEDGE.

AFFIANT'S SIGNATURE AND TITLE

PRINCIPAL INVESTIGATOR

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

DANISH A. JABBAR, MD 1153 E. GANNON DRIVE
FESTUS, MO 63028

Subscribed and sworn to before me at St. Louis, Missouri
(City and State)

this 23rd **day of** January, **20** 18.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

DANISH A. JABBAR, M.D.

1153 E Gannon Drive, Festus, Missouri 63028

636-282-0380 (o)
djabbar@amicistrials.com

- Experienced physician and accomplished student, known for outstanding performance and motivation.
- Recognized by colleagues for excellent patient care, definitive and collaborative approach to team efforts.
- Experience with clinical and basic science research including at Washington University in St Louis with Dr. Anthony Muslin, including publication of article in the Cleveland Clinic Journal of Medicine
- Credentials include:
  - Previous Clinical Instructor, Division of Hospital Medicine, Washington University in St. Louis
  - Board Certified in Internal Medicine, August 2009
  - Graduating Resident of the Year, St. Luke's Hospital, 2009
  - Intern of the Year, St. Luke's Hospital, 2006-2007
  - Outstanding evaluations from all attending physicians at St. Luke's Hospital and Washington University.
  - United Kingdom's General Medical Council Licensure (limited), 2005-2006

CLINCAL TRIALS EXPERIENCE

AMICIS CLINICAL TRIALS
Chief Executive Officer and Principal Investigator for Amicis Clinical Trials. Studies conducted:

Braeburn Pharmaceuticals
Phase III trial involving subcutaneous injectable depot of Buprenorphine

Biorassi Pharmaceuticals
Phase III trial involving topical Permethrin for treatment of Scabies

Chelsi Pharmaceuticals
Phase III trial involving inhaled steroids in Asthmatic subjects

MD Global Incorporated
RADAR-PGx Registry involving Pharcogenomics evaluation for medication adjustment in adult subjects

5/17/17

PUBLICATION & PRESENTATIONS

Getting the iron out: Preventing and treating heart failure in transfusion-dependent thalassemia CLEVELAND CLINIC JOURNAL OF MEDICINE ***CCJM*** 2007 Nov;74(11):807-816

Congestive heart failure is the most common cause of death in patients with thalassemia, as chronic accumulation of iron due to regular blood transfusions leads to biventricular systolic dysfunction and death at a very young age. The quantity of iron deposited in the heart is a key determinant of outcome. Early diagnosis and intensive chelation of the cardiac iron can avert heart failure and its fatal outcome.

Rab4 mRNA expression in Akt-2 null mice cardiac tissue

WASHINGTON UNIVERSITY IN ST LOUIS

Basic science research done under tutelage of Dr Anthony J Muslin

Dr Muslin is the Oliver M Langenberg distinguished professor of medicine and was the director of the cardiology research fellow fellowship program. The research involved insulin metabolism and cardiac hypertrophy in Akt-2 knock out mice.

79-Year-Old Female with Tako Tsubo Cardiomyopathy. Jabbar, D.A. Jacobs, Daryl

- Poster describing Broken Heart Syndrome, a disease becoming more evident in post-menopausal women, was presented at American College of Physicians (ACP) poster competition.
- First runner-up among 95 entrants, Missouri ACP Chapter Meeting, Lake of the Ozarks, MO: 2006
- Represented Missouri in national competition, San Diego, CA: 2007

INTERNAL MEDICINE

MIDWEST MEDICAL PRACTITIONERS, ARNOLD, MISSOURI

Primary care physician, October 2015 to date

As owner and solo practitioner, I see a variety of adult internal medicine pathologies. I do joint injections, I&D's, wellness exams

MERCY JEFFERSON HOSPITAL, FESTUS, MISSOURI

Hospitalist, April 2014 to October 2015

Mercy Jefferson is a 251 bed high volume community based hospital working under the Mercy health network. I managed acute adult inpatient medicine patients

- Management of TCU (ICU stepdown), cardiac and general medicine patients
- Old procedures including central lines, LP, arthrocentesis and paracentesis

MEMORIAL HOSPITAL, BELLEVILLE, ILLINOIS

Hospitalist, Southern Illinois University, September 2011 to March 2014

Memorial Hospital is a well recognized community based institution in the city of Belleville with magnet status. The service is well integrated with the various sub specialties providing efficient management of the hospitalized patient

8/17/17

ST. MARYS HEALTH CENTER, INPATIENT CONSULTANTS OF MISSOURI. ST LOUIS, MO

Academic Hospitalist, Department of Hospital Medicine, June 2010 to August 2011

St Mary's is a community based hospital with affiliated residency training programs in Internal Medicine and Gynecology. Hospital Medicine is one of the institution's most dynamic departments with both academic and clinical Hospitalist. With emphasis on team work and multidisciplinary approach, Hospitalist at St Mary's imparts excellent experience in this constantly evolving field

- Experience as full time Hospitalist in a high volume setting
- Patients are seen on general medical floors, on acute SSM Rehabilitation Institute and Psychiatry wards. Work also allows to admit patients for surgical consults and medical subspecialties.
- ICU coverage
- Supervising teaching resident teams

WASHINGTON UNIVERSITY IN ST. LOUIS, BARNES JEWISH HOSPITAL, St. Louis, MO

Clinical Instructor, Division of Hospital Medicine, 2009 - 2010

Barnes Jewish Hospital is the largest medical institution in the state of Missouri with over 1200 beds and has consistently been rated as one of the top hospitals in the United States. Ranked 9th best medical center overall by US News & World report in 2009, the hospital is a major tertiary care center involved in the training of residents and fellows in a myriad of Medical and Surgical specialties. The Division of Hospital Medicine is amongst the largest in the institution with 50 Hospitalists taking care of admitted Internal Medicine patients.

- Worked as Clinical Instructor in the School of Medicine at a faculty position.
- Managed patients on the general medical service, oncology, bone marrow transplant, liver, lung and combined kidney-pancreas transplant and cardiology patients.
- A dedicated Procedures rotation involving placement of ultrasound guided central lines, lumbar puncture, arthrocentesis, paracentesis etc. I supervised residents during such procedure

POST - GRADUATE TRAINING

ST. LUKE'S HOSPITAL, St. Louis, MO

Residency, Internal Medicine, 2006 – 2009

St. Luke's is a 450 bedded teaching, community based hospital having affiliation with Saint Louis University. Regarded by Healthgrades amongst the top 50 hospitals in the nation and the only one in Saint Louis, St. Luke's caters to a large and diverse population which provides the basis for an excellent teaching program. Solucient Healthcare database recognizes St. Luke's as a top 100 hospital for six out of the past 10 years

- Excellent hands-on training in procedures, in-patient and out-patient management
- Key rotations have included MICU, Cardiology, Medical Floors, ER, Ambulatory care
- Earned outstanding evaluations from all faculty

4/17/17

AWARDS & ACHIEVEMENTS

ST. LUKE'S HOSPITAL, St. Louis, MO

- Intern of the Year, 2006-2007.
- Graduating Resident of theYear, 2009
- First Runner-Up, Clinical Vignette Category, ACP Poster Competition, Missouri Chapter, 2006.

AGA KHAN UNIVERSITY HOSPITAL (Pakistan's premier medical institution):

- Attained 4th position of 750 candidates countrywide in residency test.
- Attained 13th position of 1,200 candidates in nationwide selection test for internship.
- Ranked 13th of 900 candidates in nationwide Proficiency Evaluation test given by Pakistan Medical Association.

LICENSURE & CERTIFICATIONS

- ***Board Certified in Internal Medicine*** August 2009
- ***Licensed,*** State of Illinois, September 2011
- ***Licensed,*** State of Missouri, Physician & Surgeon unrestricted license
- ***Certified,*** Educational Commission for Foreign Medical Graduates (ECFMG), 2004
- ***Licensed,*** General Medical Council, United Kingdom, #6044189 (limited), 2005 – 2006
- ***Completed and Passed,*** Professional Linguistics and Assessment Boards, Parts 1 & 2, 2005
- ***Licensed,*** Pakistan Medical and Dental Council, Registration#33557-S (full unrestricted)
- ***Fellow,*** College of Physicians & Surgeons, Part 1 in Medicine & Allied, 1997
- ***Certified,*** ACLS/BLS, American Heart Association

EDUCATION

UNIVERSITY OF KARACHI, Karachi Medical & Dental College, Pakistan
Bachelor of Medicine / Bachelor of Surgery (M.B.B.S.), 1997
Ranked top 30% of graduating class.

CLINICAL EXPERIENCE

ST. ALEXIS HOSPITAL, St. Louis, MO 2005

Observership, Department of Psychiatry

- Gained exposure to U.S. hospital system.
- Presented patients to attending physician and performed administrative duties.

3/17/17

WREXHAM MAELOR HOSPITAL, WREXHAM, WALES, UNITED KINGDOM
Senior House Officer
2005

- Large district general hospital in the borough of Wrexham in north east Wales
- Initially worked as an extern in geriatric medicine and later on, joined as SHO
- Assigned to a fixed team and performed all duties including calls
- Experience allowed me to gain first hand experience of the NHS

FATIMID FOUNDATION, Karachi, Pakistan 2004 - 2005
Resident Medical Officer, Department of Hematology

- Registered indigent patients with hemoglobinapathies and bleeding disorders.
- Managed patient care under supervision.

RAFIQUEE SHAHEED HOSPITAL, Karachi, Pakistan 2002
Resident Medical Officer

- Hospital run by the City District Govt. Karachi, providing subsidized services
- Excellent clinical exposure to a variety of medical problems in the indigent

ZIA CLINIC, Karachi, Pakistan
Medical Physician (2003 – 2005)

- Independently managed patients in group practice.

Junior Assistant (1999 – 2000)

- Assisted senior physician in treatment of broad variety of pathologies and diseases in under-served community.

LIAQAT NATIONAL HOSPITAL AND POST-GRADUATE INSTITUTE FOR MEDICAL AND HEALTH SCIENCES, Karachi, Pakistan 2003
Emergency Medicine, Casualty Medical Officer, Dr. M. Razi Masood, Supervisor

- Performed rotations in cardiac bay, acute trauma bay, and triage services of large, tertiary-level hospital.
- Served as team leader, providing patient management independently or under supervision.

AGA KHAN UNIVERSITY HOSPITAL, Karachi, Pakistan
Residency, Department of Cardiology. Dr. Khawar Kazmi, Supervisor (200-2001)

- Performed rotations in CCU, Coronary Step-Down Unit, and cardiac wards of large teaching hospital.
- Handled one of four calls, providing cardiac emergency coverage; assisted in procedures.

Transitional Year (1997 – 1998). Supervisor, Dr. Farhat Hashmi

- Performed six-week rotations each in general surgery and cardiothoracic surgery.
- Performed one-month rotations in orthopedics, internal medicine, and emergency medicine.

8/17/17

Study list

Braeburn Protocol HS-16-555
BPN
Pain
Copernicus IRB

Crestovo Protocol CDI-001
C-DIFF
CP101 - Full Spectrum Microbiota
Copernicus IRB

Biorasi Protocol MAP-8184
Scabies
Permethrin Cream 5%
Integ Review IRB

Cron Source Protocol CCD-05993AA3-01
Monitor
(Chiese Sponsor)
Astima
Beclomethasone Dipropionate 80mg
Chesapeake IRB

Danish A. Jabbar, M.D.

4158 E. Gravion Drive
Festus, MO 63028
Office: 314-200-4513
Fax: 636-282-0384
danish.jabbar@bracketrials.com

CURRENT PROFESSIONAL EXPRIENCE

Bracket Trials, Festus, MO — **2013 - Current**
Principal Investigator

Assist in recruitment of additional research studies, especially through professional/clinical, industry, and academic relationships. Provide input to the Site Director with regard to study protocols (e.g., with respect to enrollment/ retention potential, office capacity and capabilities, profit potential, and other determinants of success). Provide input to the Site Director as to which studies to pursue. Conduct medical office visits with all subjects in active studies, and ensure compliance with requirements of protocols for said studies. Act as liaison with study monitors for active studies. Represent Bracket Trials at conferences sponsored by potential clients (i.e., pharmaceutical firms) as requested. Provide assistance to Patient Recruitment personnel in recruiting patients for studies, with a particular emphasis upon working with other physicians and hospitals.

EDUCATION

St. Alexis Hospital, St. Louis, MO — 1997

RESIDENCIES

St. Luke's Hospital, St. Louis, MO — **2006 - 2009**

BOARD CERTIFICATIONS

- Board Certified in Internal Medicine — 2009
- Licensed, State of Illinois — 2011
- Licensed, State of Missouri, Physician and Surgeon Unrestricted License

Signature: _____ Date: 9/26/16

- Certified, Educational Commission for Foreign Medical Graduates (ECFMG) 2004
- Licensed, General Medical Council, United Kingdom, #6044189 (limited) 2005
- Completed and Passed, Professional Linguistics and Assessment Boards 2005
- Licensed, Pakistan Medical and Dental Council, Registration #33557-S
- Fellow, College of Physicians and Surgeons 1997
- Certified, ACLS/ BLS, American Heart Association

AWARDS

St. Luke's Hospital, St. Louis, MO

- Intern of the Year 2006 – 2007
- Graduating Resident of the Year 2009
- First Runner-Up, Clinical Vignette Category, ACP Poster Competition 2006

Aga Khan University Hospital

- Attained 4th position of 750 candidates countrywide in residency test
- Attained 13th position of 1,200 candidates in nationwide selection test for internship
- Ranked 13th of 900 candidates in nationwide Proficiency Evaluation Test given by Pakistan Medical Association

POSITIONS

- Principal Investigator, Bracket Trials, Festus, MO 2013- Present
- Primary Care Physician, Midwest Medical Practitioners, Arnold, MO 2015- Present
- Hospitalist, Mercy Jefferson Hospital, Festus MO 2014- 2015
- Hospitalist- Southern Illinois University, Memorial Hospital, Belleville, IL 2011 - 2014
- Academic Hospitalist, St. Mary's Health Center, St. Louis, MO 2010 - 2011
- Clinical Instructor, Washington University St. Louis, St. Louis, MO 2009 - 2010
- Observership, Department of Psychiatry, St. Alexis Hospital, St. Louis, MO 2005
- Senior House Officer, Wrexham Maelor Hospital, Wrexham, Wales, UK 2005
- Resident Medical Officer, Hematology, Fatimid Foundation, Karachi, Pakistan 2004 - 2005
- Medical Physician, Zia Clinic, Karachi, Pakistan 2003 – 2005
- Casualty Medical Officer, Liaqat National Hospital, Karachi Pakistan 2003
- Resident Medical Officer, Rafiquee Shaheed Hospital, Karachi, Pakistan 2002

Signature _____ Date: 9/26/16

- Resident, Aga Khan University Hospital, Karachi Pakistan 2000 - 2001
- Junior Assistant, Zia Clinic, Karachi, Pakistan 1999 - 2000

PUBLICATIONS

Getting the Iron Out: Preventing and treating heart failure in transition-dependent thalassemia
Cleveland Clinic Journal of Medicine 2001

CLINICAL RESEARCH EXPERIENCES – CURRENTLY CONDUCTS PHASE I TO PHASE IV CLINICAL TRIALS

Adolescent Smoking Cessation, Phase IV

Double blind, Alzheimer's, phase III

Binge Eating Disorder, phase III

Double blind, Bipolar Disorder, phase III

Double blind, COPD, phase II/III

Double blind, Liver Cirrhosis, phase II

Double blind, Type 1 Diabetes, phase III

Double blind, Type 2 Diabetes, phase III

Hyperlipidemia, phase III

Major Depressive Disorder, phase II

Opioid Dependence Disorder, phase III

Peripheral Arterial Disease, phase IV

Scabies

COPD

Asthma

Diabetic Gastroparesses

Crohn's Disease

Pediatric, Adolescent and Adult Constipation

Tardive Dyskinesia

Adolescent Schizophrenia

Acne Vulgaris

Multiple Sclerosis

Cystic Fibrosis

Irritable Bowel Syndrome

Signature: _____ Date: 9/28/16

Traveler's Diarrhea

Heart Failure

Low Back Pain

SCHIZOPHRENIA COMPOUNDS

Asenapine

Cariprazine

Glutamate Antagonist

Nicotine Agonist-AZ compound

Olanzapine vs. Aripiprazole

Olanzapine vs. Risperidone

Paliperidone Palmitate

Quetiapine-

Ziprasidone-

DEPRESSION

Agomelatine

Lexapro

BIPOLAR DISORDER

Cariprazine

Paliperidone

Quetiapine

Ziprasidone

DEMENTIA

A7 agonist

Abeta

Abeta Phase I Genentec

Asenapine

Bifeprunox

Catie Trial-AD

Dimebon

Florbetapir (AV-45) PET imaging

Signature: _____ Date: 7/26/16

Nicotine agonist

Memantine

Mesifonate

Quetiapine

Rezerem

Ziprasidone IM

CHILD/ ADOLESCENT DEPRESSION/ BIPOLAR/ SCHIZOPHRENIA

Depakote

Lexapro

Olanzapine

Risperidone

Ziprasidone

OTHER

Acute Asthma Episode Studies.

Allergic Rhinitis Studies.

Amgen – Anemia in nursing home residents Studies.

Bi-Sexual Dysfunction Studies.

Binge Eating Disorder Studies.

Cardiokine – Anti-Hyponatremia Studies.

Cirrhosis Studies.

COPD Trials.

COPD Studies.

Dementia Studies.

Diabetic Foot Ulcer Studies.

Diabetes Mellitus Type I Studies.

Diabetes Mellitus Type II Studies.

Gastro paresis Study.

HPV Studies.

HSV Type I Studies.

HSV Type II Studies.

Irritable Bowel Syndrome Studies.

Signature: _____ Date: 7/25/16

JAK Inhibitor to Treat Chronic Asthma Studies.

JAK Inhibitor to treat Rheumatoid Arthritis Studies.

Janus Kinase Inhibitor 1 and 2 (JAK)

Liver Cirrhosis Studies.

Lundbeck Antianxiety

Merck – Rotavirus Diarrhea Studies

Methylnaltrexone – Opioid constipation Studies.

Mild to Moderate Alzheimer's Studies.

Moderate to Serious Plaque Psoriasis Studies

MS Studies.

Neuromyelitis Optica

OA Studies.

Obesity Studies.

Otitis Externa.

Pain Medication Studies.

Pre-Ejaculation Dysfunction Studies.

Psoriasis Studies.

RA Studies.

Scabies

Skin Infection Studies.

Smoking Cessation Studies.

Tardive Dyskinesia Studies.

Wood Infection Studies.

Signature: _____ Date: 9/26/16

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: February 28, 2019
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c))

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator: Danish Jabbar, MD

Address 1	Address 2		
1153 E. Gannon Drive			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Festus	MO	USA	63028

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select one of the following)*

☒ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for Item 3

Name of Medical School, Hospital, or Other Research Facility: Bracket Trials

Address 1	Address 2		
1153 E. Gannon Drive			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Festus	MO	USA	63028

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — CONTINUATION PAGE for Item 4

Name of Clinical Laboratory Facility: Medpace Reference Laboratories LLC

Address 1	Address 2		
5365 Medpace Way			
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Cincinnati	Ohio	USA	45227

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — CONTINUATION PAGE for Item 5

Name of IRB: Copernicus Group IRB

Address 1	Address 2		
One Triangle Drive Suite 100	P.O. Box 110605		
City	**State/Province/Region**	**Country**	**ZIP or Postal Code**
Research Triangle Park	North Carolina	USA	27709

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

Sami Anwar, MBBS

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

IIS-16-555: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Enriched-Enrollment Withdrawal, Multicenter Study to Evaluate the Efficacy and Safety of a Long-Acting Subcutaneous Injectable Depot of Buprenorphine (CAM2038) in Subjects with a Recent History of Moderate to Severe Chronic Low Back Pain Currently Treated with Opioids

8 PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select one of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☒ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any, the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study, and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

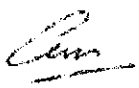
1 Complete all sections. Provide a separate page if additional space is needed.

2 Provide curriculum vitae or other statement of qualifications as described in Section 2.

3. Provide protocol outline as described in Section 8.

4 Sign and date below.

5 FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)*	11 SIGNATURE OF INVESTIGATOR	Sign
11/09/2016		

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

CLINICAL TRIAL AGREEMENT

This **CLINICAL TRIAL AGREEMENT** (this "**Agreement**") is made and entered into 8 November 2016 (the "**Effective Date**"), by and among Bracket Trials located at 2630 N Columbia Center Blvd., Richland, WA 99352 (the "**Institution**") and **Medpace, Inc.**, with its principal office located at 5375 Medpace Way, Cincinnati, Ohio 45227 (the "**CRO**").

WHEREAS, Braeburn Pharmaceuticals, Inc. ("**Sponsor**") is sponsoring a clinical research study on the compound CAM2038 (the "**Study Drug**"), entitled "A Phase III, Randomized, Double-Blind, Placebo-Controlled, Enriched-Enrollment Withdrawal (EEW), Multicenter Study to Evaluate the Efficacy and Safety of a Long-Acting Subcutaneous Injectable Depot of Buprenorphine (CAM2038) in Subjects with a Recent History of Moderate to Severe Chronic Low Back Pain Currently Treated with Opioids" (the "**Study**"), in accordance with the Study protocol number HS-16-555, as may be amended from time to time by Sponsor (the "**Protocol**");

WHEREAS, CRO is a contract research organization which has been contracted by Sponsor to manage and administer the Study;

WHEREAS, Institution possesses expertise in the conduct and performance of clinical studies and has the appropriate facilities and personnel to conduct the Study;

WHEREAS, Danish Jabbar, MD, an employee of the Institution acting within the scope of his/her employment shall serve as the principal investigator ("**Investigator**") for the Study and has the necessary qualifications, training, knowledge and experience to conduct such a clinical trial; and

WHEREAS, CRO desires that Institution participate in the conduct of the Study in accordance with the Protocol and the terms and conditions of this Agreement, and Institution desires to participate in the conduct of the Study in accordance with the Protocol and the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties, intending to be legally bound, agree as follows:

1. SCOPE OF WORK.

(a) Scope. Pursuant to the terms and conditions of this Agreement, the Institution and the Investigator will conduct the Study in accordance with the Protocol. A copy of the Protocol has been provided to Institution and Principal Investigator and is hereby incorporated by reference, together with any and all amendments thereto, into this Agreement. Institution and Investigator acknowledge that this is part of a multi-center clinical study.

(b) Investigator and Institution.

(i) The Study will be conducted under the direction of the Investigator. Investigator shall be responsible for the oversight and direction of the Study at Institution in accordance with the terms of this Agreement, Applicable Laws (defined in Section 1(e)) and Institution policies and procedures. The Institution acknowledges and agrees that it is responsible for (A) the actions, performance, and conduct of the Investigator, and (B) Investigator's compliance with all of Investigator's obligations set forth in this Agreement. Any failure by the Investigator to perform or satisfy an obligation herein shall be considered a breach of this Agreement by Institution.

(ii) The Investigator will, at minimum, assume all those responsibilities assigned to principal investigators by applicable United States Food and Drug Administration ("**FDA**") regulations and the requirements of any other applicable federal or state regulatory authorities or government officials or authorities (individually, an "**Agency**" and collectively, "**Agencies**"). The Institution and Investigator shall ensure that only individuals who are appropriately trained and qualified will assist in conducting the Study as sub-investigators (each a "**Sub-Investigator**"). The Investigator may delegate duties and responsibilities to Sub-Investigators only to the extent permitted by Applicable Laws. The Institution and Investigator shall maintain a current written record of the duties and responsibilities delegated to the Sub-Investigators. The Institution and Investigator shall provide this record of delegated duties and responsibilities to CRO and Sponsor as required by the Protocol, Investigator's Brochure, all Applicable Laws or upon CRO or Sponsor's written request. All Sub-Investigators shall work under the supervision of the Investigator and agree to be bound by the same terms as the Investigator under this Agreement.

(iii) Prior to commencing the Study, Institution shall ensure that the Investigator, and any Sub-Investigators, have provided CRO and Sponsor with all requested regulatory documents, including without limitation, a completed and signed (A) financial disclosure statement in a form reasonably acceptable to Sponsor and CRO (as may be updated from time to time upon CRO or Sponsor's reasonable request) and in accordance with FDA regulations contained in 21 C.F.R. Part 54, (B) Form FDA 1572 Statement of Investigator, which shall also include the names of all Sub-Investigators participating in the Study (if any), (C) a signed and dated Curriculum Vitae and/or other relevant documents evidencing qualifications of the Investigator and any Sub-Investigator, and (D) a copy of the signature page of each of the Protocol and the Investigator's brochure for the Study (the "**Investigator's Brochure**") signed by Investigator and any Sub-Investigator.

(iv) Institution and Investigator may not reassign the conduct of the Study to a different Investigator without CRO and Sponsor's prior written authorization. Institution represents that Investigator is an employee of Institution. If during the course of the Study, Institution becomes aware that Investigator plans to leave the employment of Institution, or if, at any time during the Study, Investigator is unable or unwilling to perform his or her duties as Investigator, Institution and Investigator shall promptly notify CRO and Sponsor in writing of the same, and if feasible, propose a substitute principal investigator. Institution and Investigator shall provide CRO and Sponsor with any reasonable documentation and assistance requested by CRO or Sponsor to evaluate the qualifications of any proposed substitute principal investigator. CRO shall notify Institution of Sponsor's decision either to continue the Study with the proposed substitute investigator or to terminate the Study at Institution. In the event of termination, Investigator and Institution will perform the transition activities set forth in Section 10 in addition to complying with other terms applicable to termination. In the event of continuation, the departing and substitute principal investigators shall sign documentation provided by CRO or Sponsor acknowledging their respective ongoing obligations and duties as former and current Investigator, including having any substitute principal investigator agree to the terms and conditions of this Agreement and, prior to commencement of participation, such substitute principal investigator must provide the documentation described in Section 1(b)(iii). The substitution of an Investigator pursuant to this Section 0 shall not affect the obligations of Institution under this Agreement. If Investigator ceases to be an employee of Institution, Sponsor and CRO shall have the right to transfer the conduct of the Study from Institution to the Investigator's new practice, and Institution agrees to fully cooperate with Sponsor, CRO and Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

(v) CRO and Sponsor reserve the right to terminate or replace Investigator if there is information available to CRO or Sponsor indicating that (A) Investigator failed to perform the obligations of Investigator set out in the Protocol, the Applicable Laws, or this Agreement, (B) Investigator has repeatedly or deliberately failed to comply with the requirements of any Agency, or (C) Investigator has submitted false information to CRO or Sponsor.

(c) Personnel.

(i) The Institution and Investigator shall ensure that only individuals who are appropriately trained and qualified will assist in conducting the Study and the Institution and Investigator shall be responsible for the conduct and direct supervision of all such personnel, subcontractors, Sub-Investigators, agents, affiliates or any other person or entity participating in the Study (collectively with the Investigator, the "**Study Personnel**") and, in addition, shall ensure the Study Personnel's compliance with the terms of this Agreement.

(ii) Institution and Investigator agree to promptly notify CRO and Sponsor or any such designee in the event any Study Personnel is reported to or comes under investigation by any licensing board, independent ethics committee or institutional review board, and further agrees to promptly discontinue the use of any such personnel in connection with the Study unless Sponsor consents in writing to the continued use of such personnel.

(iii) Institution and Investigator represent and warrant that all Study Personnel (A) are informed of and agree to abide by the terms of this Agreement, (B) are subject to the same obligations of confidentiality as those which apply to Institution and Investigator under this Agreement, and (C) have signed agreements which vest ownership in and to Institution of any intellectual property and proprietary rights they might have in the results of their work, including Sponsor Inventions (defined in Section 8(d)) and Study Documentation (as defined in Section 3(a)), as required for Institution and Investigator to fulfill their obligations hereunder.

(d) Facility. The Institution shall provide appropriate resources and facilities (the "**Facility**") so the Investigator can conduct the Study in a timely and professional manner and according to the terms of this Agreement. Institution and Investigator shall conduct the Study at the Facility which shall be identified as Institution's location on the first page of this Agreement, or at such other facility as CRO, Sponsor and Institution may agree to in writing and which shall be listed on the Form FDA 1572.

(e) Applicable Law. The Investigator and Institution shall, and shall ensure that all Study Personnel shall, perform the Study in conformance with (i) this Agreement, the Protocol, the Investigator's Brochure, the Informed Consent Form (as defined in Section 1(f)) and other Study related documents provided by the CRO or Sponsor or a designee, (ii) an ethical manner and in a manner that appropriately protects the safety, security and well-being of the Study subjects and any data arising from the Study, (iii) the Form FDA 1572, and (iv) applicable local, state and federal laws, rules, regulations and guidelines relating to the conduct of the Study and the conduct of clinical investigations, including, but not limited to, the United States Federal Food, Drug, and Cosmetic Act and its implementing regulations, the U.S. Anti-Kickback statute, the False Claims Act, the Physician Payments Sunshine Act, 21 C.F.R. Parts 50, 54, 56 and 312, International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, the U.S. Foreign Corrupt Practices Act and all similar laws of other countries where services are being provided, all privacy, security and data protection laws and other relevant professional standards, and (v) all generally accepted good clinical practice ("GCP") standards as applicable to drug studies, including, without limitation, (A) the requirements for obtaining and ensuring that an IRB (defined in Section 1(f)) provides initial and continuing review and approval of the Study, (B) the requirements for obtaining informed consent in accordance with the requirements of the FDA and the IRB reviewing the Study, in a form reasonably acceptable to CRO and Sponsor and incorporating the appropriate confidentiality provisions, and (C) the requirements for obtaining prior written authorization to use and disclose health information for research in accordance with the Health Insurance Portability and Accountability Act of 1996 and any regulations and

official guidance promulgated thereunder and codified at 45 C.F.R. Parts 160 & 164, as may be amended from time to time ("**HIPAA**"), as well as all applicable state laws, and as further set forth in Section 6 (Sections 1(e)(iv) and (v) collectively, "**Applicable Laws**").

(f) Institutional Review Board. Institution and Investigator will obtain and ensure that an institutional review board constituted and operating in compliance with all Applicable Laws (the "**IRB**") provides prior written approval of Institution's, Investigator's and Study Personnel's conduct of the Study at Institution, including approval of the Protocol, the informed consent form to be executed by all Study subjects enrolled by Institution and Investigator in the Study (the "**Informed Consent Form**"), and the HIPAA authorization (as further described in Section 6). Institution and Investigator will (i) be responsible for providing CRO and Sponsor or Sponsor's designee with a copy of each such approval, together with all relevant correspondence with the IRB regarding such approval, and (ii) coordinate with the IRB to obtain review and approval in writing of any amendments to the Protocol or the Informed Consent Form. Institution and Investigator will further ensure that the Study is subject to continuing oversight by the IRB and agree to promptly forward to CRO and Sponsor, copies of all correspondence to and/or from the IRB concerning the Study within 24 hours of receiving such notification.

(g) Subject Enrollment. Institution and Investigator shall enroll subjects into the Study in accordance with the Protocol, the Investigator's Brochure and other Study related documents provide by CRO or Sponsor, as well as any specific limitations set forth in the Protocol or Schedule A. Institution and Investigator shall use all reasonable efforts to complete enrollment in the Study by the enrollment closing date, if any, set forth in the Protocol or as otherwise notified in writing to Investigator or Institution by CRO or Sponsor. The Study period may be extended or shortened and the number of Study subjects Institution may enroll in the Study may be changed at Sponsor's sole discretion. Institution acknowledges that the Study is part of a multi-center study and agrees that when the enrollment goal for the multi-center study as a whole is reached (or if enrollment is closed by CRO or Sponsor or if the Study is put on hold by FDA), enrollment will be closed at all sites, including Institution, regardless of whether Institution has reached its individual enrollment goal.

(h) Study Subject Informed Consent. Institution and Investigator will obtain a signed Informed Consent Form, in the form approved by Sponsor, CRO, and the responsible IRB, from all Study subjects at the time of enrollment in the Study and before each Study subject begins participating in the Study. Any revisions to the content of the Informed Consent Form (including any revisions made during the course of the Study and/or requested by the IRB) must be approved by Sponsor and CRO in writing before they may be used. Institution and Investigator will ensure that every Study subject signs an amended Informed Consent Form each time the content of the Informed Consent Form is amended. Institution will maintain a signed original of the Informed Consent Form in the Study subject's records. The Investigator will maintain a log, in compliance with HIPAA and other Applicable Laws, of persons screened as potential Study subjects. Institution will allow Sponsor, CRO, and/or their respective designees to inspect signed Informed Consent

Forms or make photocopies thereof during monitoring visits or audits. Institution and/or Investigator will, within one working day from its occurrence, notify CRO, Sponsor or their respective designee of any failure to obtain an executed Informed Consent Form and/or HIPAA authorization from a Study subject at the time of enrollment.

(i) Protocol Amendments. Except on an emergency basis as expressly set forth in this Section 1(i), no change in the Protocol will be made by Institution or Investigator unless the Protocol is modified by a written amendment signed by Sponsor and such amendment is approved by the responsible IRB. Sponsor may at any time make an administrative change to the Protocol upon written notice to the Institution and Investigator. If it is necessary to change the Protocol on an emergency basis for the safety of the Study subjects, Institution and Investigator will use their best efforts to contact Sponsor and CRO in advance, but if advance notice is not possible, Institution and Investigator will notify Sponsor, CRO, and the responsible IRB no later than 24 hours after the Protocol amendment is implemented. Any emergency change to the Protocol must immediately be followed by a written Protocol amendment signed by the Sponsor and approved in accordance with this Section 1(i).

(j) Adverse Events. Institution and Investigator will promptly notify CRO, Sponsor and/or their respective designees of any safety information, serious adverse drug experience or adverse event, as that term is defined in 21 C.F.R. 312.32(a), and the severity thereof, associated with the Study or the Study Drug. Institution and Investigator shall provide adverse event reports to CRO and Sponsor and/or their respective designees, in accordance with, the Protocol, Applicable Laws or such Sponsor guidelines with respect to the reporting of adverse events as Sponsor or CRO may supply to Institution or Investigator from time to time. Without limiting the foregoing, in the event that any serious adverse event and/or serious suspected adverse reaction occur, the Institution and Investigator shall notify CRO and Sponsor and/or their respective designee and the applicable IRB within twenty-four (24) hours. Institution and/or Investigator will (i) provide CRO and Sponsor with all associated documentation (e.g., lab reports, death summary, operative reports, etc.) for each such adverse drug experience or adverse event, and (ii) fully cooperate with CRO and Sponsor in the investigation of any such adverse drug experience or adverse event.

(k) Additional Research. No additional research may be conducted on Study subjects during the conduct of the Study unless it is approved by Sponsor in writing. Such prohibited research activities include, but are not limited to, analyses of Biological Samples (defined in Section 3(d)) from Study subjects that are not required under the Protocol.

(l) Conflict of Interest; Disclosure.

(i) Institution shall comply with any and all of its conflict of interest and other policies in connection with the conduct of the Study. This Agreement is not related to or made to influence the purchase, sale, referral or recommendation of any product or service sold or marketed by Sponsor. Institution and Investigator have been selected to conduct the Study because of their experience, expertise and resources and not, in any way, as an inducement to, or in return for, past, present or future prescribing, purchasing, recommending, using, dispensing or granting preferential formulary status for any Sponsor product.

(ii) Institution agrees to keep accurate records regarding payments made and expenses incurred in connection with the Study and shall provide CRO and Sponsor with such information upon request. Sponsor will have the right to disclose (including on Sponsor's website) and report, as may be required by Applicable Law (including the Physician Payment Sunshine Act set forth in Section 6002 of the Patient Protection and Affordable Care Act of 2010, and similar state reporting laws), or as otherwise desired by Sponsor, (A) information relating to the services performed under this Agreement, including without limitation, all payments, reimbursement for expenses, or other transfers of value made in other than monetary form, (B) the total amount of funding (or other financial support) expected to be, or actually, provided by CRO or Sponsor for the Study, (C) identifying information concerning the Institution, the Investigator and any other Study Personnel, and (D) any other information relating to this Agreement or the Study. In connection with a permitted publication of the Study results (the "**Study Results**"), Institution and Investigator agree to disclose (1) Sponsor's funding and support of the Study, and (2) any significant financial or other relationship between Sponsor and Institution and/or Investigator, and/or between Sponsor and any Study Personnel.

2. PAYMENT.

(a) Budget. In consideration for the proper performance of the Study by the Institution and the Investigator under terms of this Agreement and upon approval of Sponsor or its designee, CRO will pay the payee ("Payee") designated in Schedule A appended hereto and incorporated herein by reference, Institution in accordance with the payment terms, payment schedule and the budget attached hereto as Schedule A (the "**Budget**"), upon receipt of invoices and other appropriate documentation as specified therein. Such payment shall be contingent upon performance having been conducted in accordance with this Agreement and receipt of funds from the Sponsor.

(b) Disbursements to Study Personnel. The parties acknowledge and agree that (i) the amounts payable to Investigator and the Study Personnel for services provided hereunder shall be paid to the Payee designated in Schedule A, (ii) Payee shall be responsible for disbursing payment to Investigator and Study Personnel, and (iii) Neither CRO nor Sponsor shall have any liability to Investigator or any Study Personnel for any failure of

Payee to pay such amounts. No other benefits or compensation, beyond those expressly included in the Budget, will be provided by CRO or Sponsor.

(c) Credits. Any amounts paid by CRO to the Payee for services that have not been performed, or expenses that have not been incurred, under this Agreement shall be promptly credited to CRO and used to offset any future payments owed by CRO, or be promptly refunded to CRO upon the expiration or termination of this Agreement, or earlier at the written request of CRO. Except with respect to those expenses expressly made reimbursable under this Agreement, the Institution acknowledges and agrees that the payments made by CRO under this Section 2 represent CRO's total obligations under this Agreement, and fully cover the agreed upon costs of conducting the Study.

(d) Evaluable Subjects. Unless otherwise agreed herein, payments will be made for evaluable subjects only. An evaluable subject is one who has been enrolled (randomized to treatment) and for whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied.

(e) Third Party Reimbursement. Institution and Investigator shall not, and shall ensure that no Study Personnel (i) seeks reimbursement from Medicare, Medicaid, the Study subject, or any other third party payor, whether public or private, for any costs covered by payments made or goods or services provided by CRO or Sponsor under this Agreement or otherwise incurred for conducting the Study, or (ii) seeks or retains payment from CRO or Sponsor for any item, procedure or service that is reimbursed by any patient, third-party payor or any other person or entity. The Institution hereby agrees that neither participants in the Study nor any third party will be charged for the Study Drug or any comparator drugs provided for this Study, nor shall such cost be included in any cost report to third-party payers.

(f) Taxes. Institution and Investigator are independent contractors, and CRO is not responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Institution, Investigator or any Study Personnel. The Budget contained in Schedule A is inclusive of any applicable taxes that may be required notwithstanding the preceding sentence.

(g) Reasonable Compensation. Institution and Investigator acknowledge and agree that the amounts payable by CRO under this Agreement are reasonable compensation for the work performed and represent the fair market value of the services provided by Institution, Investigator and Study Personnel under this Agreement and no part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services, nor are the payments intended to induce illegal referrals of business.

3. RECORDKEEPING; REPORTING.

(a) Study Documentation. Institution and Investigator shall prepare, maintain and retain complete, current, accurate, organized and legible Study Documentation (as defined below) in a manner acceptable for the collection of data for submission to, or review by, the FDA and other Agencies, and in full compliance with the Protocol, Investigator's Brochure, other Study documents, and all Applicable Laws. For purposes of this Agreement, "**Study Documentation**" includes all records, accounts, notes, reports, documents, protocols, data, results, and/or safety information collected or generated during the course of conducting the Study, whether in written, electronic, video or other tangible form, including, without limitation, the completed CRFs, worksheets, reports, radiologic examinations, observations, signed Informed Consent Forms, IRB approvals and correspondence.

(b) Provision of Data and Reports. Institution shall provide to CRO and Sponsor original CRFs or electronic CRFs for each Study subject participating in the Study and such other reports as and when required by the Protocol, Investigator's Brochure, other Study documents, or Applicable Laws. Investigator shall review all CRFs to assure their accuracy and completeness and shall assist CRO, Sponsor and/or their respective designees, upon their request, by promptly resolving any discrepancies or errors in the CRFs and in performing random audits on Study subject's records, laboratory reports, or other raw data sources underlying the data recorded in the CRFs. Institution and Investigator agree to allow, during normal business hours and upon advance notice, CRO, Sponsor and/or their representatives to have direct access to hospital records and all Study subject data for the purpose of verifying data entered in the CRF against source documents for completeness, accuracy and consistency.

(c) Retention. Institution and Investigator will (i) retain complete, accurate, and organized Study subject, laboratory, and Study Drug inventory records relating to the Study, including Study Documentation and Study Results, in a secure manner with physical and electronic access restrictions, and environmental controls appropriate to the applicable data type and in accordance with applicable industry standards, (ii) protect all such records from unauthorized use, access, duplication, disclosure, loss or damage, and (iii) retain all such records for the period of time required by Applicable Laws. Thereafter, Institution and Investigator will not, and shall ensure that Study Personnel do not, destroy such records without giving CRO and Sponsor prior written notice and the opportunity to further store such records, at Sponsor's cost and expense.

(d) Biological Samples. If so specified in the Protocol, Institution will collect and provide to CRO, Sponsor or a designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study subjects in connection with such Study subjects' participation in the Study ("**Biological Samples**") for testing that is not directly related to Study subject care or safety monitoring, including pharmacokinetic, pharmacogenomics or biomarker testing. Institution will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol and the terms and conditions of the Informed Consent Forms signed by the applicable Study subjects. CRO,

Sponsor or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, the results of such tests ("**Biological Sample Data**") will not be provided to the Institution or Study subject. Biological Sample Data will be treated as Study Documentation; therefore, if CRO or Sponsor provides Biological Sample Data to the Institution, that data will be subject to the permitted uses of Study Documentation as outlined in this Agreement. Institution and Investigator agree to use, store and dispose of the Biological Samples of Study subjects in accordance with the Protocol and the terms and conditions of the Informed Consent Forms signed by such Study subjects.

4. **ACCESS; AUDITS.**

(a) Audits and Reviews. CRO and Sponsor or their authorized representatives shall have the right, upon reasonable advance notice and during regular business hours, to (i) audit and examine the facilities used in performance of the Study, (ii) monitor the conduct of the Study, (iii) review, copy and audit all Study Documentation, Study Results and any other books, records, data and information, including all financial information, related to the Study, and all required licenses, certificates and accreditation (provided such copies do not include any unauthorized individually-identifiable information of a Study subject), and (iv) interview the Investigator, Sub-Investigators, Study Personnel and other persons who assisted in performing the Study. Study subjects' medical records will be made available where appropriate for the purpose of source document verification procedures.

(b) Cooperation. Investigator and Institution will require Study Personnel to cooperate with CRO and Sponsor and/or their respective designees during any monitoring visit or audit, including making themselves available to discuss or review records and reports related to the Study and to resolve any questions relating to such records and reports (including Study Documentation and Study Results). At the request of CRO, Sponsor or their respective designees, Institution and Investigator will promptly correct any errors or omissions in such records and reports, and agree to provide any additional data, access or assistance reasonably requested by CRO or Sponsor in connection with the Study and/or Sponsor's approval or clearance of the Study Drug.

(c) Regulatory Inspections. If any Agency (i) communicates with Institution or Investigator with respect to (A) the Study, (B) another study involving Investigator or Study Personnel which might have an impact on Study enrollment, or (C) the qualification of Institution or Investigator or any Study Personnel to perform the Study, (ii) conducts, or gives notice of its intent to conduct, an inspection at any Facility or of any Study Documentation or Study Results, or (iii) takes, or gives notice of its intent to take, any other regulatory action with respect to the Study or with respect to any activity of Institution, the IRB or Investigator that could reasonably be expected to impact any data or clinical activity under the Study, then, in each case, Institution shall notify CRO and Sponsor of such contact or notice in writing within twenty-four (24) hours after such contact or notice. CRO and Sponsor shall have the right to be present at, and to participate in, any such inspection or regulatory action with respect to the Study. Institution and Investigator shall make reasonable efforts to segregate, and not disclose, any Sponsor Inventions, Study Documentation, Study

Results, Biological Sample Data or other materials, correspondence and documents that are not required to be disclosed during such an inspection, including financial data and pricing information.

(d) Regulatory Correspondence. Institution and Investigator shall provide CRO and Sponsor with copies of submissions and other correspondence to and from any Agency related to the Study. If FDA issues a Form FDA 483 Notice of Observations relating to the Study or another Agency issues a similar document, or if there are any Agency requests or observations, or any information or documentation issued by any Agency, Institution or Investigator relating to the Study, as applicable, shall send a copy of such document promptly to CRO and Sponsor. CRO and Sponsor shall have the right to comment on the draft response to any such document or submission before it is sent to the applicable Agency. No such response shall contain any false or misleading information. Institution agrees to consider CRO and/or Sponsor's comments in good faith, and shall consult with CRO and Sponsor, as applicable, in the event that Institution disagrees with or is unable to accept any of the proposed comments.

(e) Regulatory Assistance. At the request and expense of CRO or Sponsor, Institution and Investigator shall (i) assist Sponsor in the preparation and submission of investigational new drug applications, new drug applications, any other premarket or marketing applications or other regulatory report relating to the Study or the Study Drug, and any amendments or supplements to the foregoing, (ii) attend meetings with the FDA and any other Agency regarding such applications and the associated approvals, and (iii) provide such other reasonable assistance as Sponsor or CRO may request in connection with regulatory matters relating to the Study or the Study Drug; provided, that in each case the scope of assistance requested shall be limited to providing information about the Study Documentation, Study Results, and conduct of the Study.

5. CONFIDENTIALITY.

(a) Definition. **"Confidential Information"** shall be the confidential and proprietary information of Sponsor, and means (i) the terms and conditions of this Agreement, (ii) all information disclosed to Institution, Investigator, or Study Personnel, directly or indirectly, by or on behalf of Sponsor or CRO in connection with the Study or this Agreement, including, but not limited to, the Protocol, Study Drug(s), CRFs, results, data, reports, scientific, technical, economic and business information, commercialization and Study strategies, trade secrets, know-how and all other types of intellectual property, whether in writing or by electronic, oral or visual transmission, and (iii) all data and information developed, generated or collected by CRO, Institution, Investigator or Study Personnel in connection with the performance of the Study, including, but not limited to, all Sponsor Inventions, Study Documentation and Study Results.

(b) Exclusions. The above obligations of confidentiality shall not apply to the extent Confidential Information:

(i) is at the time of disclosure or becomes, through no fault of the Institution and Investigator, part of the public knowledge under circumstances involving no breach of this Agreement;

(ii) was already lawfully in the Institution's or Investigator's possession on the date of disclosure to the Institution or Investigator, as applicable, other than by previous disclosure by CRO, Sponsor and/or their respective designees, and not subject to prior confidentiality obligations and as evidenced by Institution's or Investigator's written records at the time of disclosure;

(iii) is lawfully and in good faith made available to the Institution or Investigator from any third party without restrictions on disclosure, and who did not, to Institution's or Investigator's knowledge, derive it, directly or indirectly, from CRO, Sponsor and/or their respective designees; or

(iv) is developed by the Institution or Investigator independently, without the use or benefit of Confidential Information, and as evidenced by competent written records.

(c) Obligations of Confidentiality. During the term of the Agreement and for a period of seven (7) years after completion of the Study at all sites, Institution and Investigator will not, and will ensure that Study Personnel do not, use the Confidential Information for any purpose other than to conduct the Study, or disclose any Confidential Information (whether by publishing, disseminating, delivering, or otherwise making it available) to any third party, without the prior written consent of Sponsor. To protect Confidential Information, Institution and Investigator agree to (i) limit dissemination of Confidential Information to only those Study Personnel having a "need to know" such Confidential Information of the Sponsor in order to conduct the Study, (ii) advise all Study Personnel who receive Confidential Information of the confidential nature of such information, (iii) have appropriate agreements with Study Personnel sufficient to enable them to comply with the confidentiality and non-disclosure obligations contained herein, and (iv) use all of the same measures to protect the Confidential Information from disclosure that Institution uses to protect its own confidential information.

(d) Permitted Disclosures. The Institution's and Investigator's obligations of non-disclosure and non-use of Confidential Information shall not apply to the extent the Institution and Investigator are required by Applicable Laws to disclose Confidential Information, provided the Institution and the Investigator (i) notify CRO and Sponsor in writing as far as possible in advance of the disclosure so as to allow Sponsor to take legal action to protect its Confidential Information, (ii) disclose only that Confidential Information required to comply with the legal requirement, (iii) continue to maintain the confidentiality of Confidential Information with respect to all other third parties, and (iv) cooperate with CRO and Sponsor, at Sponsor's expense, to minimize the disclosure of Confidential Information.

(e) Return of Confidential Information. If requested by CRO or Sponsor, Institution and Investigator will return all Confidential Information to Sponsor, at Sponsor's expense, or at Sponsor's election destroy all Confidential Information and certify such destruction in writing, in either case except for Confidential Information required to be retained at the Study site by applicable regulations. However, Institution may retain a single archival copy of Confidential Information in its legal department files for the sole purpose of determining the scope of obligations incurred under this Agreement.

(f) Specific Performance. Institution and Investigator agree that any violation of the terms of this Agreement relating to the disclosure or use of Confidential Information may result in irreparable injury and damage to Sponsor not adequately compensable in money damages, and for which Sponsor may have no adequate remedy at law. Institution and Investigator acknowledge and agree that, if those disclosure terms and restrictions on use are violated, Sponsor, as a third party beneficiary, may need to obtain injunctions, orders, or decrees in order to protect the Confidential Information and will be entitled to seek such remedies, in addition to any other remedies available for breach at law or in equity, without having to post a bond or show harm.

6. **PRIVACY AND HIPAA.**

(a) This Section sets forth the terms and conditions pursuant to which Institution and Investigator will disclose certain protected health information ("PHI") in the form of a Limited Data Set to CRO and/or Sponsor. Terms used, but not otherwise defined, in this Section shall have the meaning given the terms in the HIPAA Regulations at 45 CFR Part 160-164.

(i) Compliance with HIPAA. Institution and Investigator each will comply with their respective obligations as required under the provisions of HIPAA. If any party is exposed to individually-identifiable confidential information of a Study subject, such information may only be used as permitted in the Study subject HIPAA authorization, Informed Consent Form, and in accordance with Applicable Law.

(ii) Covered Entity. Institution and Investigator each represents, certifies and covenants that it is a "Covered Entity" under HIPAA. Institution and Investigator shall handle all Study Documentation, Study Results, and a Study subject's medical records in accordance with HIPAA requirements and all other Applicable Laws related to the confidentiality, privacy and security of such information.

(iii) HIPAA Authorization. Institution and Investigator shall ensure that they obtain from each Study subject a signed valid HIPAA authorization that (i) complies with HIPAA and all Applicable Laws, (ii) is, in form and substance, agreed upon in writing by CRO and Sponsor, including any modifications thereto, and (iii) allows Institution and Investigator to provide to CRO, Sponsor and its designees, and for CRO, Sponsor and its designees to (A) have access to Study subject medical records, and (B) use the Study Documentation, Study Results, and Study subject health information, for any and all purposes allowed by Applicable Law.

(iv) Use of PHI. Institution and Investigator agree that CRO, Sponsor and its designees shall be named in the HIPAA authorization, or the Informed Consent Form if no separate HIPAA authorization is used, as parties to whom Study subjects' PHI will be disclosed in connection with the Study and that such authorization or consent shall permit CRO, Sponsor, and its designees access to and use of Study subjects' PHI as may be necessary to monitor the Study and to receive and use Study Results. Institution and/or Investigator will obtain such authorizations or consents as may be required under HIPAA, FDA and other Applicable Laws to permit CRO, Sponsor, its representatives, and Agencies to exercise the rights set forth in this Agreement. Both during the Study and following its termination, Sponsor will have the unrestricted, free right to use Study Documentation and Study Results, including, without limitation, Study subjects' PHI contained therein, for any and all purposes allowed by Applicable Law. CRO will not identify the information contained in the Limited Data Set and will not contact the individuals who are the subject of the PHI contained in the Limited Data Set unless necessary for its own legal responsibilities, such as the obligation to report serious adverse events.

(v) Breach. Upon Institution's knowledge of a material breach of this Section 6 by CRO, the Institution shall provide an opportunity for the CRO to cure the breach or end the violation. If efforts to cure the breach or end the violation are not successful within a reasonable time, the Institution shall discontinue disclosure of PHI to CRO and report the problem to the Secretary of the Department of Health and Human Services or its designee. The Institution shall immediately discontinue disclosure of the Limited Data Set to the CRO if the Institution determines cure of the breach is not possible.

7. PUBLICATION.

(a) Terms. Upon completion of the Study at all sites and evaluation by Sponsor of all data from the Study, or upon early termination or abandonment of the Study at all sites, Institution and Investigator may publish, present, or otherwise publicly disclose (a "**Public Presentation**") Study Results for non-commercial purposes, subject to the following:

(i) Review Period. A copy of such Public Presentation will be given to CRO, Sponsor and/or their respective designees for review at least 60 days prior to the date of submission for Public Presentation ("**Review Period**"). Sponsor will complete its review within the Review Period and Institution and/or Investigator agree to delete any Confidential Information from the Public Presentation. Expedited reviews for abstracts or poster presentations may be arranged if mutually agreed to by Sponsor, Institution and Investigator. At the end of the Review Period, Institution or Investigator will have the right to make such Public Presentation, subject to Sections 9 and 7(a)(iii) below.

(ii) Patent Filings. If CRO or Sponsor notifies Institution or Investigator during the Review Period that it desires patent applications to be filed on any Sponsor Inventions (defined in Section 8(d)) disclosed or contained in the Public Presentation, Institution and Investigator will defer disclosing the Public Presentation for a period (not to exceed 120 days) sufficient to permit Sponsor or its designee to have filed or to file any desired patent applications.

(iii) Multi-Center Trials. The Study is part of a multi-site study, and publication of the results of the Study conducted at the site shall not be made before the first multi-site publication by Sponsor. No Public Presentation by Institution or Investigator will be made until Study Documentation and Study Results from all sites have been received and analyzed by Sponsor, or the multi-center study has been terminated or abandoned at all sites. If a publications committee, or a committee of principal investigators, is formed for publication of results of the multi-center clinical study or if Sponsor intends to publish the results of the multicenter Study, any separate publication by Institution or Investigator will be delayed until the initial publication by the committee or Sponsor or a determination is made by the committee not to make such publication. If (A) the committee or Sponsor does not produce an initial draft of a manuscript or abstract of results from all sites within 18 months of database lock following completion of the Study at all sites, and (B) the committee or Sponsor has not notified the Institution or Investigator that it intends to produce a manuscript or abstract in a timeframe satisfactory to Institution and Investigator after the 18 month period, then Institution and Investigator may make a Public Presentation of the Study Results subject to the terms and conditions of this Section 7. Sponsor may use, refer to and disseminate reprints of scientific, medical and other published articles related to the Study which may disclose the name of Investigator, Study Personnel, and/or Institution without further permission or consideration other than what is paid under this Agreement.

(b) Media. Institution and Investigator shall not, and shall ensure that Study Personnel do not, engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet (including any social media), related to the Study, this Agreement, or the Study Drug, including advertisements for the enrollment of Study subjects, without the prior written consent of the Sponsor. This provision does not prohibit Public Presentation in accordance with Section 7(a) above.

(c) Use of Name. The Institution and Investigator shall not use the name, symbols and/or trademarks of CRO or Sponsor in any form of publicity in connection with the Study unless explicitly approved by CRO and Sponsor, as applicable, in advance. Institution and Investigator agree that, in accordance with Applicable Law, Sponsor may make public the amount of funding provided hereunder for the conduct of the Study and may identify Institution as a site at which the Study was conducted and to identify those individuals responsible for conducting the Study, including the Investigator, as part of this disclosure. Institution represents that it has or shall obtain the Investigator's consent to this disclosure.

8. OWNERSHIP OF MATERIAL; INTELLECTUAL PROPERTY.

(a) Pre-Existing Intellectual Property. It is recognized and understood that the existing inventions, technologies, know-how, ideas, processes, techniques, algorithms, programs, discoveries, improvements, devices, pharmaceuticals, biologics, products, concepts, designs, prototypes, samples, models, technical information, materials, drawings, specifications and works of authorship existing as of the Effective Date hereof, and all patents, copyrights, trade secret rights and other intellectual property rights therein of CRO, Sponsor or the Institution and Investigator are their separate property and are not affected by this Agreement, and no party hereunder shall have any claims to or rights in such separate inventions and technologies of the other parties.

(b) Study Documentation and Study Results. All Study Documentation as well as data contained within Study Documentation generated by CRO, the Institution, Investigator or Study Personnel, in the course of conducting the Study or provided to the Institution, the Investigator or Study Personnel pursuant to this Agreement, are and shall remain Sponsor's property. The completed CRFs, the final report (if applicable), and all other results of the Study, including the Study Results, shall also be owned by Sponsor and considered Study Documentation. Neither CRO nor Sponsor shall own subject medical records.

(c) Materials. Sponsor shall own all right, title and interest in and to any equipment, materials, methods, documents, data, software and information supplied by or on behalf of, or purchased at the expense of, Sponsor in connection with the Study.

(d) Sponsor Inventions. The entire right, title and interest in and to any invention, development, know-how, methods, operations, formulas, copyrights, trade secrets, ideas, improvement, discovery, or other intellectual property rights made or conceived by Institution, Investigator, or Study Personnel, whether or not patentable, alone or jointly with others, resulting from the Study, or from the performance of the Protocol or the use of the Study Drug or other Confidential Information (each a "Sponsor Invention"), shall be promptly disclosed by Institution and Investigator in writing to Sponsor. All Sponsor Inventions shall be owned solely by Sponsor. Neither Institution nor Investigator shall take any action that is inconsistent with Sponsor's sole ownership of Sponsor Inventions, Study Documentation and Study Results. The Institution and Investigator, as applicable, shall have exclusive ownership of any inventions or discoveries conceived or reduced to practice solely by the Institution or Investigator, as applicable, that are not Sponsor Inventions.

(e) Assistance. Institution and Investigator shall, and shall cause all Study Personnel to, promptly disclose each Sponsor Invention to Sponsor in writing. Institution shall, and shall cause Investigator and any Study Personnel to, where applicable and consistent with the requirements of this Agreement, (i) execute all documents and, at Sponsor's expense, perform all acts reasonably requested by CRO or Sponsor to effect or document the assignment of any Sponsor Invention to Sponsor, and to perfect, enforce, or evidence Sponsor's ownership of or rights to such Sponsor Invention, and (ii) assist Sponsor in

preparing, prosecuting, obtaining, registering, maintaining, defending and enforcing, at Sponsor's request and sole expense (for actual costs incurred), discretion and exclusive control, all patents (including any divisions, continuations, continuations-in-part, reissues, renewals, extensions or the like of any such patent) or equivalents thereof (including certificates of invention), copyrights, trade secret rights and other proprietary rights in and to the Sponsor Inventions in any and all countries as may be determined by Sponsor.

(f) Assignment and License. Institution and Investigator shall assign, and shall require all Study Personnel to assign, in writing to Sponsor, through a present grant of rights, all rights, title and interest, if any, in and to each such Sponsor Invention and Study Documentation. Institution and Investigator, on behalf of itself and Study Personnel, each hereby assigns all right, title and interest in and to (i) all of its intellectual property and proprietary right, title and interest in and to all Sponsor Inventions and the Study Documentation to Sponsor, and (ii) all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. In the event that the right, title and interest in any Sponsor Invention or Study Documentation cannot be assigned to Sponsor, Institution and Investigator shall, and shall ensure that Study Personnel and/or inventor (as applicable) shall, grant to Sponsor (or its designee) the irrevocable, worldwide, exclusive, fully-paid, royalty-free right and license, with the right to sublicense through multiple tiers, to such Sponsor Invention or Study Documentation (or such other similar rights to the maximum extent permitted by Applicable Laws).

(g) No Conflicts. Institution and Investigator represent that (i) they are not bound by any agreement, commitment, arrangement or court order, or any other existing or previous business relationship that violates, conflicts with or prevents the full performance of Institution's and Investigator's duties and obligations to CRO or Sponsor under this Agreement, and (ii) they have no present obligations to assign or license to any person or entity other than Sponsor, any Sponsor Inventions, Study Documentation, Study Results, or other intellectual property covered by this Section 0.

(h) No Other Rights. Except as expressly set forth above, none of CRO, Sponsor, Investigator, or Institution transfers to the other by operation of this Agreement, implication, estoppel or otherwise, any patent right, copyright right, trademark right or other intellectual property right of any party.

9. SUPPLY; MATERIAL TRANSFER; RETURN OF MATERIALS; EQUIPMENT.

(a) Supply of Study Materials. In accordance with Applicable Laws, CRO and Sponsor shall not provide the Study Drug to the Institution or the Investigator before all required approvals and authorizations for the conduct of the Study have been obtained. During the Study, CRO or Sponsor or a designee shall provide to the Institution, at Sponsor's expense, the Study Drug, placebo and other compounds or agents that are required under the Protocol for the performance of the Study (collectively, the "**Study Materials**"). All Study Materials supplied to the Institution shall remain the exclusive property of Sponsor.

(b) Use of Study Materials.

(i) The Study Materials shall be used by the Institution, Investigator and Study Personnel only for the performance of the Study in accordance with the Protocol, this Agreement and Applicable Laws. Institution shall ensure that only Investigator and Study Personnel required to conduct the Study will be provided access to the Study Drug. Institution and Investigator shall handle, store, ship and dispose of Study Materials in accordance with the Protocol and any written instructions provided by CRO, Sponsor (or Sponsor's designee), and in compliance with all Applicable Laws, including, but not limited to, those governing hazardous substances.

(ii) Institution and Investigator will maintain appropriate control of supplies of Study Drug and will not administer or dispense Study Drug to anyone other than an enrolled Study subject who has executed the Informed Consent Form. Institution and Investigator shall maintain complete and accurate records showing the disposition and return of the Study Drug, including recording the dates and amounts of Study Drug (i) received, (ii) dispensed or administered, including the Study subjects to whom the Study Drug was dispensed or administered, (iii) disposed of, damaged, or lost, and (iv) returned to Sponsor or CRO.

(iii) Institution will not allow Sponsor property, Study Drug, or Study Materials to be moved, altered, disassembled, reverse engineered or in any way tampered with, except by authorized representatives of the Sponsor or as expressly permitted under this Agreement. Neither Institution nor Investigator will chemically, physically or otherwise modify Study Drug.

(iv) Institution will not attempt or purport to assign, pledge, transfer, encumber, or grant any security interest in the Study Drug, Study Materials, or any other Sponsor materials or equipment to any third party.

(c) Equipment. If Sponsor or CRO provides equipment to the Institution or Investigator, such equipment shall be used by Institution and Investigator only for the performance of the Study and in accordance with any written instructions of use provided by the equipment manufacturer, CRO, or Sponsor. Such equipment is the property of the Sponsor or Sponsor's designee and shall be returned, at Sponsor's expense, to CRO, Sponsor (or Sponsor's designee), upon CRO or Sponsor's written request or upon completion of the Study. Institution and Investigator will use reasonable care to maintain such equipment while in its possession, provided that Sponsor shall be responsible for maintenance and repair costs due to normal wear and tear.

(d) Return of Study Materials and Equipment. Upon completion or termination of the Study, or upon request of CRO or Sponsor, all Study Drug, Study Materials, and other Sponsor materials or equipment furnished to the Institution, Investigator or Study Personnel by CRO, Sponsor or Sponsor's designee shall be promptly returned as directed by CRO or Sponsor. Shipping costs relating thereto will be paid by CRO or Sponsor.

10. TERM; TERMINATION.

(a) Term. This Agreement shall commence on the Effective Date and shall continue in force until the Study has been completed at the site, unless earlier terminated pursuant to this Section 10.

(b) Termination by CRO.

(i) CRO may suspend or terminate the Study or terminate this Agreement, in whole or in part, with or without cause at any time, effective upon 30 days' advance written notice.

(ii) In the event of a material breach of this Agreement by the Institution or Investigator, CRO may immediately (A) suspend the Study at the site, and/or (B) terminate this Agreement; provided, that before exercising its right to terminate this Agreement, Sponsor has given the Institution written notice of the nature of the default and such default is not cured within 10 days after Institution's receipt of such notice.

(iii) CRO may immediately terminate this Agreement, upon written notice to Institution, upon suspension or termination of the Study.

(c) Termination by Institution. Institution may terminate this Agreement in the event of a material breach by CRO of this Agreement, provided that Institution has given CRO written notice of the nature of the default and such default is not cured within 30 days after CRO's receipt of such notice.

(d) Suspension of Study. Performance of the Study may be suspended by Sponsor, Institution or Investigator at any time for health or safety reasons, if, in the reasonable opinion of Investigator, Institution, or Sponsor, continuation represents an unacceptable risk to the Study subjects. In the event of any such determination by Sponsor, Sponsor, as applicable, shall promptly notify Institution and Investigator of the same by telephone. In the event of any such determination by Institution and/or Investigator, Institution and/or Investigator shall promptly notify CRO and Sponsor of the same by telephone twenty-four (24) hours prior to suspending performance, and, within twenty-four (24) hours after such notification, shall provide CRO and Sponsor with a detailed written explanation for the suspension of the Study, including any associated documentation in support thereof. In the event of such suspension of the Study, Institution and Investigator shall immediately cease enrollment of Study subjects into the Study.

(e) Effect of Termination.

(i) Immediately upon receipt of a notice of termination, the Investigator and Institution shall stop screening and enrolling subjects into the Study and shall, as directed by CRO, cease conducting Study procedures on subjects already enrolled in the Study, as soon as reasonably possible, and to the extent medically permissible, to minimize any adverse medical effect to such enrolled Study subjects and to cease incurring any additional Study expenses. Institution and Investigator shall continue to perform the follow-up testing and provide the data required under the Protocol on subjects already participating in the Study, unless instructed otherwise by Sponsor or CRO in writing, and the terms of this Agreement shall continue to apply to such follow-up testing and data. Sponsor or its designee shall have the right to assume full control of the terminated Study. Investigator and Institution shall provide such other reasonable assistance, at Sponsor's expense, as is necessary to ensure a smooth and orderly transition of the Study that will not involve any disruption of the Protocol, if the Study is continuing, and to ensure the full transfer of Study Documentation, Study Results, and CRO's and Sponsor's ability to verify all data.

(ii) Within 30 days of termination of this Agreement or completion of the Study (whichever comes first), Investigator will submit a final written report to CRO and Sponsor or Sponsor's designee regarding the Study, and Institution and Investigator will return all Study Materials, any unused Study Drug, CRFs (whether or not completed), all Sponsor property, Study Documentation and other materials or equipment that were furnished to Institution, Investigator or Study Personnel by or on behalf of CRO, Sponsor or their respective designees.

(iii) Within 30 days after the termination of this Agreement or completion of the Study (whichever comes first), an accounting shall be conducted by the Institution, subject to verification by CRO or Sponsor, and Institution shall deliver to CRO and Sponsor such final accounting of all Study subjects participating in the Study and the visits completed in accordance with the Study during the term of this Agreement, and, if applicable, all reasonable direct costs incurred in connection with any transfer of the Study as described in Section 10(e)(i). Within 30 days of delivery or receipt of the final accounting, either Institution shall refund to CRO any excess amounts paid by CRO or CRO shall pay any additional amounts owed to Institution, as the case may be, provided that CRO or Sponsor has received the items described in Section 10(e)(ii), applicable invoices and other supporting documentation satisfactory to CRO and Sponsor. In no event shall CRO or Sponsor be obligated to pay any invoices submitted after the time period for submitting final invoices set forth in Schedule A has expired. CRO and Sponsor or its designee shall have the right for a period of one (1) year after the payment made under this Agreement to audit the Institution's books and records with respect to such accounting. Only those services and expenditures compensated under the Budget shall be compensated upon termination, and Sponsor and CRO shall not be responsible for any lost profits or lost opportunities.

(iv) If the Institution or Investigator has been paid any amounts which have not been earned hereunder as of the date of termination, they shall promptly return to CRO all such unearned funds within 30 days.

11. INSURANCE.

(a) Institution Insurance Coverage. During the performance of this Agreement, the Institution shall, at its own expense, carry and maintain professional liability insurance coverage and general liability insurance coverage sufficient to cover Institution's and Investigator's obligations hereunder, which coverage shall, in the event of any claim, be primary to any insurance coverage that CRO or Sponsor may maintain.

(b) Insurance Requirements. Institution possesses and shall carry and maintain the following insurance in amounts no less than that specified for each type:

(i) malpractice insurance/ medical liability insurance with limits of not less than $1,000,000 per medical incident and $3,000,000 per medical aggregate for each physician performing services under this Agreement, including, but not limited to, the Investigator;

(ii) commercial general liability insurance, including premises and operations coverage, and professional liability (financial / E&O) insurance, with limits of not less than $5,000,000 per occurrence and $5,000,000 per annual aggregate covering each person performing services on behalf of Institution under this Agreement, including, but not limited to, the Investigator, and covering Institution's obligations, including indemnification obligations, set forth in this Agreement; and

(iii) worker's compensation insurance in the amount required by applicable state law.

(c) Period of Coverage; Certificate. The coverage shall remain in place through consistent cover or tail coverage throughout the term of the Study and, if the policy is a claims-made policy, for an additional five (5) years after completion of the Study. The Institution and Investigator shall, at CRO or Sponsor's written request, have its insurance carrier for such insurance furnish to CRO or Sponsor a certificate that such insurance is in force, such certificate to indicate any deductible and/or self-insured retention and stipulate that such insurance will not be canceled or reduced while this Agreement is in effect without at least 30 days prior written notice to CRO and Sponsor.

12. INDEMNIFICATION; SUBJECT INJURY.

The terms and conditions of indemnification shall be set forth in a separate letter of indemnification between Sponsor and Institution. CRO shall not have any obligation to indemnify Investigator(s), Institution and/or their agents, employees and representatives.

13. REPRESENTATIONS AND WARRANTIES.

(a) Institution represents and warrants that it has the experience, capability and resources including, but not limited to, sufficient personnel and equipment, to efficiently and expeditiously perform the Study according to the Protocol and in a professional and competent manner.

(b) Investigator, who is employed by or affiliated with Institution, represents and warrants that he/she is experienced in the conduct of clinical studies in humans and desires to conduct the Study as a clinical investigator at the Institution.

(c) Institution and Investigator each represent and warrant that the execution, delivery and performance of the Agreement shall not (i) constitute a violation of any laws, (ii) infringe any patent, copyright, trademark, trade secret or other proprietary right of any third party, or (iii) constitute a violation, breach or default under any contract by which Institution or Investigator is bound.

(d) Institution and Investigator each represent and warrant that in no event shall any portion of the Study be conducted at any location other than Institution's Facility without CRO's and Sponsor's prior written permission.

(e) Institution represents and warrants that it is authorized to enforce and shall enforce the provisions of this Agreement with respect to all Study Personnel.

(f) Institution and Investigator each represent and warrant that they have not made, offered or solicited and will not make, offer or solicit (directly or indirectly) any remuneration, kickbacks or anything else of value to any person or entity in violation of the federal Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)) or any applicable state anti-kickback statutes or Applicable Law.

(g) Institution and Investigator represent and warrant that they have, and at all times during the course of the Study shall have, the appropriate licenses, permits, approvals and certifications necessary to safely, adequately and lawfully perform the Study.

(h) Institution and Investigator each represent and warrant and the Institution represents and warrants on behalf of the Study Personnel that none of Institution, Investigator, Study Personnel, or any other person who assists in performing the Study is subject to any conflicting obligations or has any financial or other interest in the outcome of the Study or has entered into any contract with respect to the Study that might interfere with the

performance of the Study or that might impair the acceptance of the resulting data by the FDA or other Agency that might create a conflict of interest. If any Study Personnel providing services hereunder is a member of a committee for any entity that sets formularies or develops clinical guidelines, then, during the term of the Study and for a period of two (2) years thereafter, Institution and Investigator shall require such Study Personnel to (i) disclose the Study Personnel's involvement with Sponsor's Study to such committee, and (ii) comply with any procedures set forth by such committee with respect thereto.

(i) Investigator represents and warrants that he/she has not been and is not currently a party to any litigation, arbitration or mediation involving the practice of medicine.

(j) Electronic Records.

(i) Institution and Investigator each represent and warrant that, either (A) all electronic records that are created, modified, maintained, archived, retrieved, accessed, or transmitted, under any records requirements set forth in FDA regulations shall comply with the requirements in 21 C.F.R. Part 11, or (B) they do not rely on electronic records or signatures, and as such are not required to comply with Part 11, and Institution shall print a paper copy of each source record that is originally recorded in electronic health record format and shall certify that such paper copy is an original record of the clinical findings.

(ii) Institution may use electronic systems to maintain or archive digital copies of original hard-copy source documents, so long as (A) the process for scanning the original hard-copy source documents is governed by a clearly defined process set out in a standard operating procedure, (B) the process for scanning an original hard-copy source document is designed to ensure that the digital copy contains all of the information found in the original source document, and (C) the digital copy of the original hard-copy source document is treated as a certified copy, which is verified by a dated signature, as an exact copy having all of the same attributes and information as the original.

(k) Institution and Investigator warrant that all of the information provided pursuant to Section 1(b)(iii) is truthful and accurate. Institution and Investigator will immediately notify CRO and Sponsor of any change in any of the information contained in the Form FDA 1572, the financial disclosure forms required by FDA regulations or any other changes to the information provided pursuant to Section 1(b)(iii). Institution, Investigator and any Sub-Investigator will also promptly notify CRO and Sponsor of any changes to their financial disclosure forms for a period of one (1) year after completion of the Study.

(l) Institution and Investigator each shall notify CRO and Sponsor in writing within forty-eight (48) hours after discovery of any facts that would cause any of the warranties given in this Section 13 to be incorrect.

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(m) No Debarment.

(i) The Institution and the Investigator each hereby represent, warrant and certify for themselves and on behalf of the Study Personnel, that it/he/she/they (i) have not been debarred by any Agency in any jurisdiction, (ii) have not been found by any court, governmental authority or Agency in any jurisdiction, including, but not limited to, the FDA and/or the U.S. Department of Health and Human Services, to have violated any Applicable Laws or received a warning by such Agency for any such violation, and (iii) have not and will not use in any capacity, assign or authorize any individual or entity including the Investigator, any Sub-Investigator or Study Personnel to perform any services in connection with the Study, the Study Documentation, or this Agreement if such individual or entity, Investigator, Sub-Investigator or Study Personnel has been (A) convicted of an offense related to any health care program in any jurisdiction, (B) found by any court, governmental or regulatory authority or agency in any jurisdiction to have violated any Applicable Laws or has received a warning by such authority or agency, (C) excluded or has performed any act or omission rendering such person eligible for exclusion from participation in any government-sponsored health care program in any jurisdiction under 42 U.S.C. Section 1320a-7 and implementing regulations, (D) debarred or performed any act or omission rendering such person eligible for debarment under Section 306 of the United States Federal Food, Drug and Cosmetic Act, or under the provisions of any other Applicable Laws, (E) placed on any clinical investigator enforcement list maintained by the FDA or any similar list maintained by European Union or other governmental authority or Agency in any jurisdiction, (F) the subject of a disqualification proceeding nor been disqualified pursuant to any Agency actions, (G) terminated from any investigation or research project by a company for clinical or medical misconduct, or (H) the subject of any litigation, arbitration, mediation, restriction or suspension involving the practice of medicine, or any other proceeding by any Agency, professional body, or similar authority in any jurisdiction.

(ii) If during the term of this Agreement, Institution, Investigator or any Study Personnel becomes aware of the debarment, threatened debarment, disqualification, or threatened disqualification of any such individual or entity, the Institution and/or the Investigator, as the case may be, shall notify CRO and Sponsor immediately.

(n) Disclaimer. THE PARTIES ACKNOWLEDGE THAT SPONSOR DISCLAIMS ANY AND ALL REPRESENTATIONS AND WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, WITH RESPECT TO THE STUDY DRUG, OR OTHER MATERIALS OR PROCEDURES TO BE ADMINISTERED IN CONNECTION WITH THE STUDY OR WITH RESPECT TO THE CONDUCT OF THE STUDY, INCLUDING, BUT NOT LIMITED TO, ANY REPRESENTATION OR WARRANTY WITH RESPECT TO THE SAFETY OR EFFICACY OF THE STUDY DRUG OR ANY REPRESENTATION OR WARRANTY AS TO QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE

Exhibit 2

OR PURPOSE, OR THAT USE OF THE STUDY DRUG WILL NOT INFRINGE THE INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

14. LIMITATION OF LIABILITY.

EXCEPT FOR A PARTY'S LIABILITY ARISING UNDER SECTION 0 (OWNERSHIP OF MATERIAL; INTELLECTUAL PROPERTY), OR SECTION 5 (CONFIDENTIALITY), IN NO EVENT SHALL SPONSOR OR ANY PARTY HEREUNDER BE LIABLE TO SPONSOR OR ANY OTHER PARTY HEREUNDER FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL OR INDIRECT DAMAGES ARISING FROM OR IN RELATION TO THIS AGREEMENT, THE PROTOCOL OR THE STUDY DRUG (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, BY STATUTE OR OTHERWISE). THIS LIMITATION SHALL APPLY EVEN IF SUCH PARTY OR SPONSOR HAS BEEN ADVISED OR IS AWARE OF THE POSSIBILITY OF SUCH DAMAGES.

15. ASSIGNABILITY.

Neither Institution or Investigator may assign any of its/his/her rights or delegate any performance under this Agreement, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner except with the prior written consent of CRO, and any purported assignment or delegation without CRO's written consent is void.

16. NOTICES.

With the exception of Study funds paid by CRO pursuant to Section 2 hereof, all notices required or permitted to be given under this Agreement shall be in writing and shall be (a) delivered personally, (b) sent by certified mail, or (c) sent by a nationally-recognized courier guaranteeing next-day delivery, to the recipients below. The parties agree that changes to the addresses below for receipt of notices under this Section 16 may be made by a letter signed by the relevant party and do not require an amendment to this Agreement signed by all parties.

If to CRO: Medpace, Inc.
5375 Medpace Way
Cincinnati, OH 45227
Attn: General Counsel

If to Sponsor: Braeburn Pharmaceuticals, Inc.
47 Hulfish Street
Suite 441
Princeton, NJ 08452
Attn: Chief Financial Officer

With a copy (which shall not constitute notice) to:
notices@braeburnpharma.com

If to the Institution: Bracket Trials
2630 N Columbia Center Blvd.
Richland, WA 99352
brackettrials@gmail.com Attn:Dr.Sami Anwar

17. **WAIVER; SEVERABILITY.**
No waiver of any term or condition of this Agreement, whether by conduct or otherwise in any one or more instances, shall be deemed to be or construed as a further or continuing waiver of such term or condition, or of any other term or condition of this Agreement. If any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect, then, to the fullest extent permitted by Applicable Law and if the rights or obligations of any party will not be materially and adversely affected, (a) such provision will be given no effect by the parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect, and (c) the parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with Applicable Law and achieves, as nearly as possible, the original intention of the parties, except that if the invalid, illegal or unenforceable provision was essential to the intended purpose of this Agreement, then the party who was to receive the benefit of the invalid, illegal or unenforceable provision has the option to void this Agreement.

18. **AMENDMENT; COUNTERPARTS; ELECTRONIC SIGNATURES.**
No terms, conditions, understanding or agreement purporting to amend, modify, vary or waive the terms of this Agreement shall be binding unless made in writing and signed by an authorized representative of each party hereto. This Agreement and any amendment hereto may be executed in several counterparts, each of which shall be deemed an original but taken together shall constitute one and the same instrument. For the convenience of the parties, Institution consents to electronic communication and electronic signatures being equal to signatures inked on paper. This Agreement may be delivered electronically by email or facsimile transmission of executed signature pages. The parties agree that any signature delivered by email or facsimile transmission shall have the same force and effect as an original signature. Therefore, any communication between the parties bearing an electronic signature will have the same force and effect as a document signed and inked on paper. Electronic signature includes a scanned copy of a signature, a typed signature, or the click of a mouse on an "I agree" icon or button. All communications that CRO provides to Institution in electronic form will be provided either: (1) via e-mail by requesting the download of a PDF or DOC file containing the communication; or (2) in the case of the ClinTrak license agreement, immediately prior to the log-in screen for ClinTrak. Institution can obtain a paper copy of an electronic communication by printing it itself or by requesting that CRO mail a paper copy, provided that such request is made within a reasonable time after CRO first provided the electronic communication.

19. CONTINUING OBLIGATION; SURVIVAL OF PROVISIONS.

Except as otherwise specifically provided herein, termination of this Agreement shall not relieve any party hereto from any obligation under this Agreement that accrued or arose from facts and circumstances in existence prior thereto. The respective rights and obligations of the parties set forth in Sections 1(e) (Applicable Law), 1(f) (Adverse Events), 1(l)(ii) (Records of Payments), 2(b) (Payment Credits), 3(b) (Provision of Data and Reports), 3(c) (Record Retention), 4 (Access; Audits), 5 (Confidentiality), 6 (Privacy and HIPAA), 7 (Publication), 0 (Ownership of Material; Intellectual Property), 9(b) (Use of Study Materials), 0 (Return of Study Materials and Equipment), 10(e) (Effect of Termination), 11(c) (Period of Insurance Coverage; Certificate), 12 (Indemnification; Subject Injury), 13(h) (No Conflicts or Financial Interest Warranty), 13(k) (Truthful Information Warranty), 13(n) (Warranty Disclaimer) and 14 (Limitation of Liability), 15 (Assignability), 16 (Notices), 17 (Waiver; Severability), 18 (Amendment; Counterparts), 19 (Continuing Obligation; Survival of Provisions), 20 (Sponsor as Third-Party Beneficiary), 21 (Independent Contractor), 22 (Governing Law), 23 (Entire Agreement; Exhibits), and any other provision that by its terms is meant to survive the termination or expiration of this Agreement, shall survive the expiration or termination of this Agreement. Termination of this Agreement by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination or that are intended by their terms to continue beyond termination.

20. SPONSOR AS THIRD-PARTY BENEFICIARY

The parties expressly acknowledge and agree that Sponsor and its affiliates shall be express third party beneficiaries of this Agreement and shall have the right (but not the obligation) to directly enforce the terms of this Agreement. For purposes of exercising such rights, CRO hereby irrevocably appoints Sponsor as CRO's true and lawful attorney-in-fact, with full authority and power in the place and stead of CRO, to take any appropriate action and to execute any instrument that Sponsor may deem reasonably necessary or advisable in order to enforce such rights. CRO hereby acknowledges, consents and agrees that the power of attorney granted pursuant to this Section 20 is irrevocable and coupled with an interest.

21. INDEPENDENT CONTRACTOR.

In undertaking to perform the respective services hereunder, Institution and Investigator are doing so as independent contractors, and not as employees or agents of CRO or Sponsor. No party shall represent itself as an agent of any other party. Neither Institution, nor any of its Study Personnel (including the Investigator or any Sub-Investigator) shall have the authority to legally bind CRO or Sponsor.

22. GOVERNING LAW.

This Agreement shall be construed according to, and governed by the laws of the State of Delaware, without regard to principles of conflicts of law.

23. **ENTIRE AGREEMENT; EXHIBITS.**

This Agreement, including the Exhibits attached hereto and the Protocol as may be amended from time to time, constitutes the full understanding of the parties with respect to the subject matter hereof, and a complete and exclusive statement of the terms of their agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each party confirms that it is not relying on any representations, warranties or covenants of any other party except as specifically set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives on the date(s) indicated below, but effective for all purposes as of the Effective Date.

Medpace, Inc.	**BRACKET TRIALS**
By: _____	By: _____
Name: _____	Name: DR SAMI ANWAR
Title: Brad Hansman Director, Site Payments & Contracts	Title: CLINICALRESEARCH DIRECTOR

Read and acknowledged by Investigator
By signing below, the Investigator acknowledges and accepts his/her obligations set forth in this Agreement and agrees to fulfill all such obligations of Investigator as set forth in this Agreement.

_____
Name: DANISH JABBAR, MD

MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

BRAEBURN PHARMACEUTICALS

PROTOCOL ID: HS-16-555

DANISH JABBAR

SITE 070

SCHEDULE A VERSION: VERSION #2

COUNTRY: US

SCHEDULE A

A1 STUDY BUDGET

Medpace, as Sponsor's payment agent, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. All fees listed include overhead, taxes, and patient stipend or travel reimbursement, as applicable. Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in USD.

A1.1 Fee for Each Evaluable Subject — $22,082

An "evaluable subject" is one who has been enrolled (enrolled to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Enrollment occurs at Visit 3.

A1.2 Total Subject Budget (Estimated) — $331,230

The total subject budget is based on 15 subjects expected to be enrolled at site.

A2 SETUP FEES & VISIT PAYMENTS

A2.1 Setup Fees

Table 1 - Setup Fees

FEES	COST
Administrative Fee	$3,000
Pharmacy Setup Fee	$1,000

Payment will be made within forty-five (45) days of:

- Sponsor declaring Institution to be ready for Study Initiation;
- IRB/EC approval; and
- Medpace's receipt of the fully-executed Agreement.

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a monthly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each monthly payment, which will be withheld until and paid with the final payment. Monthly payments will be made within forty-five (45) days after the end of each month.

Table 2 - Fees for Completed Clinical Visits for Enrolled Subjects

VISIT	FEE	24 Hour ECG	Total Visit Amount
Screening	$ 1,190.00	$ -	$ 1,190.00
Visit 2 / Transition Phase Day 1	$ 495.00	$ -	$ 495.00
Visit 3 / Transition Phase Day 8	$ 495.00	$ -	$ 495.00
Visit 4 / Open Label Week 1	$ 1,375.00	$ 425.00	$ 1,800.00
Visit 5 / Open Label Week 2	$ 675.00	$ -	$ 675.00
Visit 6 / Open Label Week 3	$ 725.00	$ -	$ 725.00
Visit 7 / Open Label Week 4	$ 675.00	$ -	$ 675.00
Visit 8 / Open Label Week 5	$ 800.00	$ -	$ 800.00
Visit 9 / Open Label Week 6	$ 675.00	$ -	$ 675.00
Visit 10 / Open Label Week 7	$ 725.00	$ -	$ 725.00
Visit 11 / Open Label Week 8	$ 675.00	$ -	$ 675.00
Visit 12 / Open Label Week 9	$ 765.00	$ -	$ 765.00
Visit 13 / Open Label Week 10	$ 675.00	$ -	$ 675.00
Visit 14 / Double-Blind Month 4, Monthly visit	$ 1,060.00	$ 425.00	$ 1,485.00
Visit 15 / Double-Blind Month 4, Weekly visit 2	$ 770.00	$ -	$ 770.00
Visit 16 / Double-Blind Month 4, Weekly visit 3	$ 770.00	$ -	$ 770.00
Visit 17 / Double-Blind Month 4, Weekly visit 4	$ 770.00	$ -	$ 770.00
Visit 18 / Double-Blind Month 5, Monthly visit	$ 930.00	$ -	$ 930.00
Visit 19 / Double-Blind Month 5, Weekly visit 2	$ 770.00	$ -	$ 770.00
Visit 20 / Double-Blind Month 5, Weekly visit 3	$ 770.00	$ -	$ 770.00
Visit 21 / Double-Blind Month 5, Weekly visit 4	$ 770.00	$ -	$ 770.00
Visit 22 / Double-Blind Month 6, Monthly visit	$ 935.00	$ -	$ 935.00
Visit 23 / Double-Blind Month 6, Weekly visit 2	$ 770.00	$ -	$ 770.00
Visit 24 / Double-Blind Month 6, Weekly visit 3	$ 770.00	$ -	$ 770.00
Visit 25 / Double-Blind Month 6, Weekly visit 4	$ 1,030.00	$ -	$ 1,030.00
Final Study Visit	$ 201.00	$ -	$ 201.00
Follow-up / Month 7	$ 201.00	$ -	$ 201.00
Follow-up / Month 8	$ 21,232.00	$ 850.00	$ 22,082.00
TOTAL PER PATIENT	15	15	15
Total number of patients	$ 318,480.00	$ 12,750.00	$ 331,230.00
TOTAL FOR ALL PATIENTS	$ 344.00	$ -	$ 344.00
Optional Booster Visit (Day 13, 14, or 15)			

A2.3 Screen Failures

Table 3 - Screen Failures

VISIT OF FAILURE	COST
Screening	$714
Screening + Visit 2	$1,685

Payment for screen failures will be made once the required number of subject(s) have been enrolled per ratio 1:2 (1 failures: 2 enrolled) for screen failures for whom Medpace has received all appropriate documentation of procedures/visits completed with the next scheduled payment owed to the Payee. Eligible screen failure payment will be based on the order (by date) of when the subject is consented.

A2.4 Final Payment

Final payment for all services performed under this Agreement will be paid to Payee by Medpace after:

- Final resolution of all queries;
- Upon final acceptance of all eCRFs;
- The receipt and approval of any outstanding regulatory documents as required by Sponsor;

- The return of all unused Study Drug, Study supplies (including any equipment provided by Sponsor) and Confidential Information to Sponsor; and
- Upon completion of all other applicable conditions set forth in the Agreement.

A2.5 Unscheduled Visit — $300

Payable with final payment. Unscheduled Visit must be entered into EDC prior to database lock and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit.

A2.6 Archiving Fee — $500

A one-time fee, payable with final payment.

A3 INVOICEABLE ITEMS

Payment will be made within forty-five (45) days of receipt of invoice and supporting documentation if applicable and requested.

A3.1 Advertising Expenses — Up to $2,500

Additional funds may be available with prior written approval from the Sponsor. Institution shall submit a copy of all advertisers' invoices to Medpace for Advertising Costs along with the invoice submitted to Medpace for reimbursement.

A3.1 Dry Ice Fee — $50 / Shipment

Medpace will pay Payee for dry ice shipments, payable upon receipt of itemized invoice from Payee and a copy of the receipt from the third-party vendor.

A3.2 IRB/REB Costs

Payments will be made at actual cost with supporting local IRB/REB invoice and/or documentation. Central IRB/REB fees will be paid directly by Medpace.

A3.3 Additional Study-necessitated Fees

Payee will be reimbursed at actual cost for any other unforeseen but reasonable procedures or costs necessitated by the Study or Protocol (and any amendments thereto) and pre-approved by Medpace/Sponsor.

A3.4 Nominal equipment

Institution may be provided during the course of the Study small items of equipment necessitated by the Study or Protocol and pre-approved by Medpace/Sponsor.

A4 MEDPACE RIGHTS

Medpace reserves the right to suspend payments due to Payee, if Principal Investigator and/or Institution do not complete data entry, query resolutions, and electronic signatures on eCRFs and/or provide regulatory documents to Medpace within timelines defined by the project team. Payments will resume once the missing or incomplete information is resolved.